

FINAL REPORT

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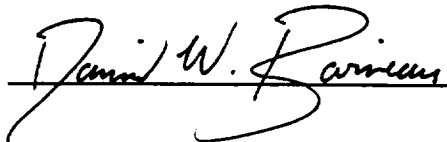
IN-SUIT DOPPLER TECHNOLOGY ASSESSMENT

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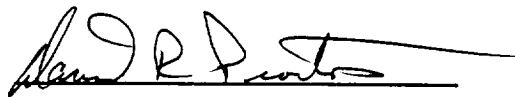
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IN-SUIT DOPPLER TECHNOLOGY ASSESSMENT

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EXECUTIVE SUMMARY

NASA scientists and physicians have been conducting research addressing the formation and circulation of air emboli ("microbubbles") in an astronaut's bloodstream when exposed to decreased atmospheric pressures. They have been especially concerned with the potential for problems which circulating air emboli could cause during extravehicular activity (EVA). To date, there have been no reports of symptoms commonly associated with circulating air emboli even though ground-based testing has predicted a significant probability of such an occurrence. Research is continuing in this area, but is being hampered by the lack of a reliable means of monitoring microbubbles in the space suit during EVA.

In many research laboratories and clinical/surgical settings, circulating microbubbles are routinely monitored using Doppler ultrasound techniques. NASA also has significant experience with this modality in altitude chamber experiments. NASA Life Sciences Engineering has consequently been directed to assess the potential for development of an automated in-suit microbubble monitoring system. To this end, LSR, Inc. has been subcontracted by GE/Government Services to generate a report detailing potential in-suit Doppler concepts and manufacturers.

LSR has completed this initial technology assessment and the results are detailed in the accompanying report. We have fully researched all background resources available to us and have contacted many cognizant researchers, scientists, and engineers to ascertain the current status of research and the "state-of-the-art" in this field.

We have also completed a survey of over sixty manufacturers in the ultrasound marketplace. We issued a "Request to Industry" which included a Questionnaire for obtaining basic information about each organization's experience and capabilities. In addition, we supplied a "specification" in our request. This specification was generalized because of many indeterminate parameters at the present time. We requested each organization to respond to this specification with a "Technical Approach" outlining potential strategies to achieving the desired design.

We received full responses (that is, both Questionnaire and Technical Approaches) to our Request from seven (7) organizations. We received partial responses from an additional eleven (11) organizations. As expected, based on the limited nature of the specifications, most responses were superficial. However, in the aggregate, they supplied us with a very good overview of industry capabilities and potential approaches to a solution. We also recognize that a number of organizations have probably chosen to withhold their "best" ideas at this early stage of review.

During the course of our assessment, we have discovered many unanswered physiological, medical, and engineering questions which must be addressed. Such basic physiological questions as "What is the best anatomical site to non-invasively monitor circulating

EXECUTIVE SUMMARY (Cont'd)

air emboli?" are still being researched. The answer to questions such as this will obviously have great impact upon the engineering design of an automated monitoring system. On the engineering side, questions such as "How does one maintain a quality signal from the preferred site during moderate body motion?" have yet to be adequately addressed.

Several organizations appear to have a very good grasp of the magnitude of the multi-disciplinary problems associated with this development. We have rated all responding organizations and attempted to identify the most outstanding. With a major caveat due to the preliminary and limited interaction which we have had with these organizations, we feel that organizations such as Hoffrel Instruments (South Norwalk, CT), the Institute of Applied Physiology and Medicine (Seattle, WA), and Medasonics (Freemont, CA) could provide credible engineering efforts for this program. There are also a number of other organizations which could conceivably provide a strong assault on this development.

We recommend that the development program should initially focus on a Feasibility Phase conducted with minimally-modified, off-the-shelf-equipment. This phase will aim at resolving the major unknowns, such as noted above.

The report presents an excellent overview of this field and will serve as a fundamental resource for the successful implementation of an in-suit ultrasound air embolism monitor.

As a final overview, the following page presents a succinct, bullet-format, itemization of the contents of this report.

EXECUTIVE SUMMARY (Cont'd)

OBJECTIVES

- Review and Present Background Research
- Survey Medical Ultrasound Marketplace
- Provide Recommendations for Future Efforts

REQUEST TO INDUSTRY

- Questionnaire: Experience and Capabilities
- Technical: General Specifications

RESULTS

- Over 60 Potential Manufacturers Identified
- 18 Questionnaire Responses
- 7 Technical Responses
- Significant Industry Interest
- Additional Limited Responses from Several Potential Vendors
- Commercial Product Spinoffs Seen as Important Incentive
- Wide Range of Capabilities, Experience, Technical Approaches
- Organizations Objectively and Subjectively Evaluated
- Organizations Ranked and Grouped

ACRONYMS

1G	One times the force of Gravity
2D	Two Dimensional
ASIC	Application-Specific Integrated Circuit
CMOS	Complementary Metal Oxide Semiconductor
CW	Continuous Wave
DCS	Decompression Sickness
DSP	Digital Signal Processing
ECLSS	Environmental Control Life Support System
EVA	Extra-Vehicular Activity
LSR	Lovelace Scientific Resources, Inc.
MHz	Megahertz
NDT	Non-destructive Testing
RF	Radio Frequency
RFP	Request for Proposal
ROM	Rough Order of Magnitude
SAM	School of Aerospace Medicine
TCD	Transcranial Doppler
WETF	Water Evaluation Test Facility

1.0 INTRODUCTION

1.1 Objectives

The objective of this program was to perform a technology assessment survey of non-invasive air embolism detection utilizing Doppler ultrasound methodologies. The primary application of this technology will be as a continuous monitor for astronauts while performing extravehicular activities (EVA's).

The technology assessment was to include:

- 1) development of a full understanding of all relevant background research and
- 2) a survey of the medical ultrasound marketplace for expertise, information, and technical capability relevant to this development.

Upon completion of the assessment, LSR was to provide an overview of technological approaches and R&D/manufacturing organizations.

1.2 Methodology

LSR initially performed a comprehensive literature survey to ensure that we were fully acquainted with all relevant background literature. This survey included searches of the National Library of Medicine (Medline) database, several engineering databases, the U.S. and World Patent databases, and various business/financial databases.

LSR also interviewed key NASA, other government, and private-sector scientists and engineers who have been involved in air embolism research and development. This step provided essential information. While many of these observations were unpublished and anecdotal in nature, they nevertheless proved to be very useful.

It was also necessary to understand the constraints associated with the current NASA space suit. Appropriate interfaces to cognizant NASA personnel were facilitated by GE/Government Services in order for LSR personnel to assure compatibility of potential approaches and recommendations with the suit environment.

Finally, based on the above foundation, LSR developed a comprehensive listing of the manufacturers and research organizations with potential for development of the desired air embolism monitoring system. We contacted each of these entities and begin to assess their suitability for the proposed task. Among our concerns were items such as:

- a) experience of key personnel in medical ultrasound,
- b) experience in signal processing,

- c) history and stability of the company,
- d) ability/willingness to produce prototype units, and
- e) experience with flight-rated (or near flight-rated) equipment.

To provide a more formal structure to this information gathering process, we developed a "Request to Industry" document which was sent to over sixty organizations. The organizations were informed that this was not an official "Request for Proposals" (RFP) and that no funds were available for development. Nevertheless, we requested that each organization provide us with information on corporate resources and technical approaches to the problem. Estimated rough-order-of-magnitude (ROM) cost figures for a prototype device were also elicited from each organization.

This report presents a compilation of our findings. We are hopeful that this assessment will provide foundational material upon which a successful development program can be built.

1.3 Scope

As we began this assessment, and expanding throughout our effort, we were impressed with a broad range of questions which will have strong impact upon the engineering design effort. Many of these questions are itemized in section 4.2 (Key Issues for Future Development) of this report. Obviously, resolution of these issues was beyond the scope of this present task.

However, we have labored to provide a foundation upon which to build solutions to these questions. To do so, we have focused the scope of this task on collecting and analyzing information from potential manufacturers, assessing the current technological state-of-the-art, surfacing as many pertinent issues as possible, and providing recommendations which could assist NASA Engineering in addressing these questions.

The development of an in-suit Doppler bubble detection system for Extravehicular Activity (EVA) will be a multi-disciplinary program with components encompassing both Life Science and Engineering fields. While treatment of the physiological issues was beyond the scope of the present assessment, their significance was fully understood in order to assure an accurate technology assessment.

2.0 BACKGROUND

To provide a comprehensive technological assessment for an in-suit monitor to detect circulating air emboli, it was necessary to build a broad-based foundation. In order to complete this task, we chose to scrutinize three different sources of information.

The first source was the published biomedical literature of the world, contained primarily in the National Library of Medicine's Medline database. The second information source was a more diverse group of databases available through the Dialog Information Services network. This collection included databases more targeted to the engineering literature, patent documentation, and corporate business information. The third information source was through contacts with key scientists, engineers, and related personnel who have first-hand experience in the air embolism research field. Our findings are summarized in the following sections.

2.1 Medical Literature Review

Immediately after program initiation, we began an intensive medical literature search in the specialized field of circulating air emboli in humans. Dr. Dick Greene, an acknowledged expert in application of ultrasound methodologies to bloodflow and imaging, was primarily responsible for collection, synthesis, and presentation of this vast amount of information.

In this section, we present a distillation of the results of the literature survey. It is formatted to provide a concise tutorial overview of the field. This review is specifically targeted to the noninvasive Doppler ultrasound detection of human air embolism and its application to microgravity decompression sickness (DCS).

2.1.1 Introduction

The selection of atmospheric pressures and gas mixtures for the Space Shuttle, Space Station, and Space Suit depends on various engineering, safety, and cost considerations. In general, as atmospheric pressure is reduced, the risk of nucleation of gas bubbles increases, thus increasing the risks of decompression sickness as described by thermodynamic theory (1,2).

Various theoretical (3,4) and ground-based experimental (5-9) studies have suggested optimal operational procedures, including atmospheric pressure, gas mixtures, and prebreathing algorithms to predict and minimize the risk of decompression sickness. Due to limitations in Space Suit technology, low pressures (4-6 psia at 100% oxygen) are required to maintain the flexibility which is essential for extravehicular activities during space missions (10,11). The problem of the competing factors of pressure versus mobility in

Space Suit design has been exacerbated by the use of standard atmospheric pressure (14.7 psia) in the Space Shuttle. This relatively high initial pressure leads to increased pressure gradients and thus the probability of DCS during EVA.

Ground-base studies have suggested that the incidence of graded DCS during EVA should be approximately 25% (12). Nevertheless, both USA and USSR astronauts presently report no incidences of DCS during 30 and 65 EVA's, respectively (9). Due to their moderating effects, in theory, on the nucleation of gas bubbles, limb constraint (13,14) and microgravity (12) have been suggested as prophylactic inhibitors of symptomatic DCS during EVA. Although difficult to document, the discrepancy between predicted and actual reports of DCS during EVA may be caused, in part, by the inherent subjectivity and unintentional under-reporting of incidences of DCS by astronauts (12).

Clearly, sensitive and specific physiological markers of subclinical and clinical DCS during ground-based and microgravity studies are required to clarify the incidences and pathophysiological sequelae of graded DCS.

2.1.2 Physiology

Despite many decades of study, the exact causal relationship of inert gas nucleation (bubbles) and DCS is not clearly understood (15-17). Depending on many environmental factors, either pre-existing microscopic nitrogen gas bubbles grow and coalesce or bubbles form *de novo* in connective tissues of joints and in blood. As atmospheric pressure is decreased, the level of supersaturation of nitrogen (the "R-value") and its surface tension dominate the growth and formation of these bubbles (2). By poorly understood mechanisms, joint soreness and pain (the "bends") can occur with severities generally proportional to the intensity and timing of the decompression. Increasing formation and migration of the gas emboli can create a graduation of symptoms from joint pain to convulsions and even death (18) should the emboli accumulate in the central nervous system.

Due to the relatively small pressure gradients which occur in manned spaceflight (approximately 15 to 4 psia) as compared to deep sea diving, only limb symptoms are expected to occur (12). These joint symptoms are stratified as:

Grade 1: joint awareness

Grade 2: mild or intermittent pain

Grade 3: persistent pain which results in compromised movement (12).

Clearly, Grade 3 symptoms could jeopardize any EVA.

It is also assumed that: 1) the lungs will effectively filter all venous blood-borne gas emboli (19), 2) no gas emboli will pass through any anatomical/physiological intracardiac

shunt, and 3) arterial blood borne gas emboli will be minimal and inconsequential (20). As previously stated, no highly reliable physiological marker of the quantitative presence of either tissue-bound or blood-borne gas emboli is presently available.

Numerous empirical studies using various O₂/N₂ mixtures for denitrogenation before EVA (5,21-23) have been undertaken to minimize the risks of DCS. Although it is generally accepted that relatively rapid pressure reduction from ambient 14.7 psia to not less than 7.8 psia, without denitrogenation, is safe and produces a DCS risk approaching zero (3, 13), there is no clear consensus on the appropriate optimal procedures to implement for a minimal, predictable DCS risk (11). This lack of consensus is again driven by the lack of an appropriate subclinical and clinical marker of the underlying pathophysiological state of DCS.

2.1.3 Doppler Method

For many years, the need for an objective method to noninvasively detect the presence, both qualitatively and quantitatively, of gas bubbles in human tissues (a physiological marker) has prompted many attempts to use ultrasound (24-28). Because of the large difference in acoustic impedances between gas bubbles and body fluids such as blood, relatively high (10 - 20 db) increases in backscattered signals arise from bubbles (29). These blood-borne bubbles create easily detectible Doppler frequency shifts (30) although of the same frequency as the surrounding acoustic scatterers (red blood cells). Indeed, the bubbles may create signal saturation of the Doppler audio spectrum.

The landmark publications of Spencer and Clarke (31) and Balldin and Borgstrom (32) demonstrated the feasibility and usefulness of Doppler ultrasound to reliably detect air-emboli in subjects with and without symptoms of DCS. A standard and subjective grading system which was proposed by these early investigators is still used by experienced operators. This grading is based on the Doppler audio signal (32):

- Grade 0: Complete lack of bubbles
- Grade 1: An occasional bubble signal within the cardiac motion signal with the great majority of cardiac periods free of bubbles
- Grade 2: Many, but less than half of the cardiac periods contain bubble signals singularly or in groups
- Grade 3: All of the cardiac periods contain "showers" or single bubble signals, but not dominating or overriding the cardiac motion signals
- Grade 4: The maximum detectable bubble signal sounding continuously through systole and diastole of every cardiac period and overriding the amplitude of the normal cardiac signal.

Due to its relative simplicity and noninvasive practicality, Doppler technique became the method of choice for most laboratories (6,7,33,34). Generally, precordial applications of both continuous wave Doppler (easy to use, but unspecific) and pulsed wave Doppler (improved spatial resolution, but more operator dependent) have been used to monitor air-emboli in the pulmonary artery or right ventricular outflow tract of the heart. This sample location was chosen to allow detection of bubbles at a central location where all blood collects from the air-emboli generating limbs, especially the legs (12). The precordial location also allows the Doppler transducer to be secured manually or by a strap in a relatively stable and constrained body location. Commercially available precordial (35, 36) and transcranial (37-39) units have become available for diving, aerospace, and surgical applications.

Presently, research studies utilizing 2 to 4 Mhz pulsed Doppler detection of blood-borne air emboli in the right heart by a precordial transducer provide the most practical and reliable method of associating venous air emboli with DCS. The method is based on the invalidated assumption of a strong pathophysiological or causal correlation between venous bubbles and DCS. The relevant importance of intravascular bubbles (which are Doppler-detected) and extravascular bubbles (which probably cause symptoms) is unclear.

Despite technical improvements over the last two decades, bubble detection (31) and screening (32) with decompression has remained subjective and qualitative (40). Unfortunately, present methods of bubble detection by Doppler remain relatively insensitive and unspecific markers of DCS (35,41,42). Reported sensitivity and specificity of bubble detection upon exposure to 4.89 psia were 77% and 61%, respectively (41). Consequently, approximately 39% of subjects without DCS (Grade 0) will have detectable bubbles (Grade ≥ 1). Conversely, approximately 23% with Grade 0 bubbles will exhibit DCS symptoms (Grade ≥ 1). Thus, the correlation of bubble scores with DCS is variable and depends upon many factors, but predominately, the accuracy of Doppler signal analysis and qualitative clinical symptom scoring (12,42,43).

In summary, although Doppler methods are presently the method of choice to detect air emboli (35,39), they create a suboptimal physiological marker of the relationship between gas nucleation and DCS. Computer control and analysis of Doppler shifted frequency spectra (44,45) should improve the sensitivity, specificity, and overall operational reliability of air emboli detection and quantification. Contrary to a recent comparative study (39), ultrasound sector imaging of air emboli (speckle) in the right heart (contrast echocardiography) may challenge standard Doppler methods in sensitivity and specificity of bubble detection (46,47). Recently developed Doppler color flow imaging may also play a role in bubble detection (48). Clearly, minimization and portability of these imaging modalities must occur before their application can be made in space, particularly in the Space Suit. Transesophageal detection would be impractical (49).

More basic ground-level (12) and microgravity studies (50) would be required to improve our understanding of the relationship between venous bubble detection and the

symptoms and clinical sequelae of DCS. Only with this information will the predictive value of air embolism detection by Doppler ultrasound, or any other modality, become operationally useful.

2.2 Other Database Searches

The literature survey detailed above was heavily reliant on numerous searches done in the National Library of Medicine Medline database. Medline is the premier online database of the world's biomedical literature.

We also surveyed several other online databases which are accessible through Dialog Information Services. The purpose of these searches was to ascertain if there is significant effort in the field of human air embolism detection being conducted in other areas of either the public or private sector. Utilizing key words which were selected to give a balanced search, ie., neither too broad nor too narrow in its results, we searched the following databases:

- a. INSPEC - A database covering the physics, electronics, and computing literature.
- b. Compendex Plus - A database providing coverage of over 4,500 engineering journals, selected government reports and books.
- c. Claims/U.S. Patent Abstracts - A database containing records from the general, chemical, electrical, and mechanical sections of the U.S. Patent Office.
- d. World Patents Index - A database containing patent documents from over 30 patent issuing authorities around the world. Abstracts are available for patents issued since 1981.
- e. Federal Research in Progress (FEDRIP) - A database providing access to information about ongoing federally-funded research projects in the fields of physical sciences, engineering, and life sciences.

Two search strings were submitted to each of these databases, without limitation of field location or keyword context. This would result in the largest number of "hits" for each database. These two search strings were:

- a. (Doppler or ultrasound) and (bubble or air) and (blood or tissue)
- b. ultrasound and transducer and blood flow and (diagnosis or monitor)

The results of these searches produced a number of citations. Most of the hits were either not particularly relevant to the in-suit Doppler bubble detection problem or were previously uncovered in the Medline searches.

The patents database searches were more fruitful, however. In particular, we discovered at least one patent which describes a multi-crystal, 2-dimensional, planar array, ultrasound transducer which might have potential for the NASA in-suit Doppler application. This 1985 patent (U.S. #4530363) details a transducer invented by A. F. Briskken and assigned to the General Electric Company (Ultrasound Division). The text of this patent is included in the appendix to this report.

2.3 Personal Interviews and Contacts

During the conduct of this study, we have had telephone conversations and meetings with many knowledgeable individuals. In addition to many individuals at the manufacturing organizations which were surveyed, we have contacted three key personnel with particular expertise in areas related to this effort. These individuals and the primary insights gained from each are detailed in the following sections.

2.3.1 Michael Powell, PhD - NASA/SD-5

Dr. Powell, a primary NASA scientist in the area of air embolism research and the author of a pending DSO proposal entitled "In-suit Doppler Ultrasound Monitoring: Detection of Gas Phase Formation in Microgravity", was most helpful in discussing many aspects of his research. In particular, LSR staff visited with Dr. Powell on two occasions (October 3rd and 24th). On these occasions, we observed Drs. Powell and Norfleet (a coworker of Dr. Powell) conducting air embolism detection experiments using a Building 37 altitude chamber. These experiments were designed to mimic the decompression stress which an EVA astronaut would incur under present suit/orbiter pressure timelines.

During these experiments, subjects exercised to varying degrees and pulmonary artery bloodflow was monitored by a technician using a Medasonics "Transpect" Transcranial Doppler Unit. This unit uses a Continuous Wave (CW) Doppler ultrasound technique to transduce the velocity of targets within its beam. The Transpect emits a relatively powerful ultrasound beam because it is primarily intended for transcranial applications. For the precordial measurements of this experiment, its power was adjusted appropriately downward. We observed the difficulty of reliably obtaining the desired bloodflow in some subjects. It was also apparent that a trained ear was often necessary to detect the presence/absence of circulating microbubbles.

During a follow-up visit to Dr. Powell's laboratory, we discussed some of the approaches to online analysis of the blood flow signal which might lead to automated air

emboli detection systems. The primary approach being pursued is to analyze the spectrum of the Doppler audio signal.

2.3.2 Glen Lutz - NASA/EC

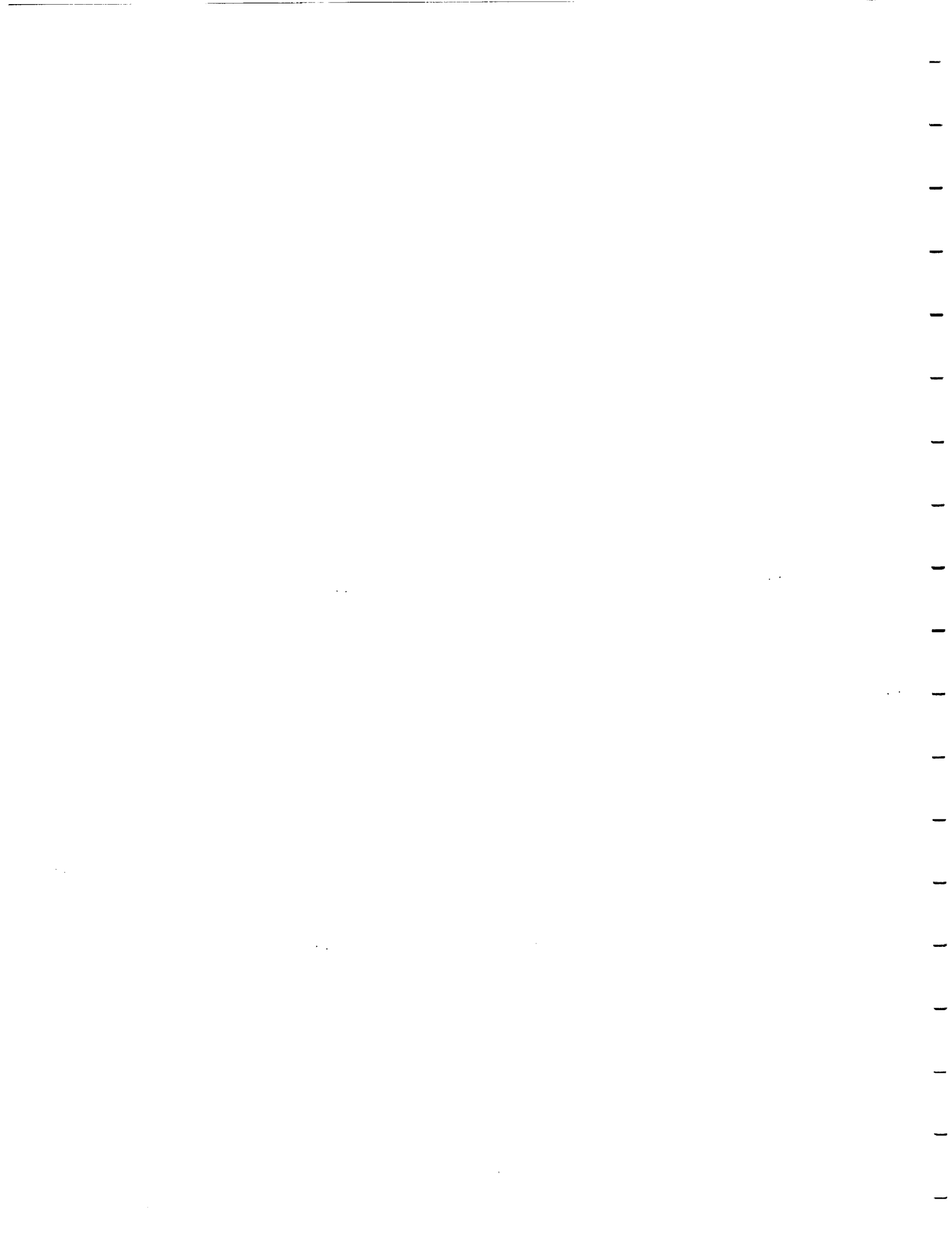
Mr. Glen Lutz provided insight into the current shuttle Space Suit during a meeting with LSR and GE personnel on October 3, 1991. Mr. Lutz was extremely helpful and was able to provide excellent information on the current operations of the suit as well as potential modifications being considered. In particular, we were able to visualize the potential volume available for an in-suit recorder within the hard upper torso of the suit.

We also discussed the present through-connector available for passing connections between the inside of the suit and the ECLSS backpack. At present, no pins are available on this connector, but a modification is being considered which would result in a larger connector with additional pins.

2.3.3 Andrew Pilmanis, PhD - USAF/Armstrong Laboratory (SAM)

Dr. Andrew Pilmanis, scientist at the USAF/Armstrong Laboratory in San Antonio, is also conducting research into air embolism detection for AF pilots. His background includes research in diving applications before joining the Armstrong Laboratory staff. Dr. Pilmanis has significant experience in ultrasound monitoring of bloodflow in order to detect circulating air emboli.

Dr. Pilmanis explained some of the research ongoing at the Laboratory and noted especially that they are becoming inclined to pursue an "imaging" approach to microbubble detection. Blood flow imaging, in its simplest modality, involves analysis and display of the amplitude of the demodulated RF echo signal. The amplitude of this demodulated echo signal, which generally falls within the audio spectrum, exhibits great sensitivity to the passage of microbubbles within the ultrasound beam. In essence, they feel that this detection scheme may be easier to use as a basis for automated detection than a scheme based on the Doppler signal.



3.0 REQUEST TO INDUSTRY

LSR developed a request for information which was sent to the broadest possible contingent of potential organizations which might be interested in this development. The full text of this "Request to Industry" is included in the Appendix to this report.

The purpose of this task was twofold:

- 1) Acquire objective data about the experience and capabilities of each organization in areas related to this effort.
- 2) Obtain a cross-section of potential technical approaches to the problem.

It must be emphasized that these technical approaches were based on a specification which we supplied and was admittedly broad and incomplete in some key aspects. Realizing this limitation, we intentionally directed each organization to supply its general thinking in the form of a "White Paper" approach.

Before sending this document, each company was contacted by telephone, if possible, to determine a personal contact and to begin to determine a level of interest/expertise for each organization.

3.1 Content of Request

The primary contents of the Request to Industry are outlined below. Section 3.1.1 describes the "Questionnaire" portion of the Request and Section 3.1.2 describes the "Specifications" portion. The specifications were given as general guidelines to be addressed by each organization's Technical Approach.

3.1.1 Questionnaire

The Questionnaire portion of the Request to Industry asked the following questions:

- 1) *How many years has your organization been in the ultrasound marketplace?*
- 2) *How many cumulative engineering person-years of experience does your current staff have in design of medical ultrasound equipment?*
- 3) *Does your organization have experience in design of battery-operated, medical, ultrasound equipment (Y/N)? If yes, approximately how many cumulative engineering person-years?*

- 4) *Does your organization have experience in design of flight equipment (Y/N)? If yes, please explain.*
- 5) *Does your organization have experience in design of ultrasound equipment specifically for circulating microbubble detection (Y/N)? If yes, please explain.*
- 6) *What are your organization's unique strengths in the design of ultrasound equipment?*
- 7) *What patents or intellectual property does your organization hold which could be relevant to this project?*
- 8) *Will your organization be submitting a "Description of Technical Approach" by Friday, November 1, 1991 (Y/N)?*

3.1.2 Technical Approach

Each organization was requested to submit a "Technical Approach" which would outline the organization's general direction in the proposed development effort. The technical approach was intended to indicate the level of experience and innovation within each organization. LSR supplied a set of basic specifications, although very limited, in the Request to Industry. Because there were, and continue to be, many areas requiring further definition, the specifications were somewhat generalized. This led to a variety of approaches within the various responses. The specifications supplied in the Request to Industry are shown below. The drawing referenced in this section is included in Appendix C of this report.

Introduction

This document is a broad definition of a small, battery-powered, ultrasound-based instrument capable of monitoring micron-sized bubble activity in the pulmonary artery bloodflow of an astronaut in a Space Suit. Other monitoring sites may also be considered. Once configured, the instrument must operate unattended during Extravehicular Activity.

In one potential configuration, the system would consist of a low-profile transducer located on the astronaut's chest (worn under a cooling garment made of a "spandex-like" material with imbedded tubing for circulating water). All processing electronics would also be located inside the Space Suit. The output signal(s) may either be recorded on a small recording device/module mounted inside the Space Suit or telemetered from the Space Suit.

A concept utilizing a multiple-crystal transducer is shown in simplified form on the attached drawing. This concept could potentially track a moving vessel. However, this is representative only, and any/all other approaches are welcome and encouraged.

Specifications

- 1) *Transducer-to-Site Interface: self-attaching/adhering. Stable and continuously operable without operator manipulation after initial attachment.*
- 2) *Artifact Rejection: Capable of continuously monitoring bubble activity with little artifact during slow upper body movements.*
- 3) *Dynamic Range: Sufficient dynamic range to detect and record bubble echoes without saturation or distortion.*
- 4) *Transducer Size: Low profile, comfortably worn under the cooling garment.*
- 5) *Power: Battery-powered, minimum 6 hour capacity.*
- 6) *Weight: Breadboard < 3 lb
(Flight model weight less than 0.5 lb)*
- 7) *Volume: Breadboard < 50 cu. in.
(Flight model volume less than 5 cu. in.)*
- 8) *Operating temperature: 60 - 100 °F (15 - 38 °C)*
- 9) *Operating atmosphere: 100% Oxygen @ 4 psia*

3.2 Organizations Supplying Full Responses

Seven (7) organizations responded completely to our Request to Industry. Each organization's response is summarized below. For ease of assimilation, we have distilled the essence of each response and attempted to present each in a somewhat consistent manner. The full, unabridged responses are included in the Appendix to this report.

There are many notable organizations which did not provide significant responses to our Request to Industry. Many of the larger medical ultrasound organizations (Acuson, ATL, Toshiba/Diasonics, GE, HP, Interspec, Philips, Siemens/Quantum, Shimadzu) were among this group. It is expected that the R&D arms of the larger organizations cannot

divert from their primary directions of development. They will not respond unless the request is perceived to fall within a rather well-defined, pre-existing corporate strategy. This is unfortunate because of the great amount of ultrasound design expertise which exists within the larger organizations.

As for the responses which we did receive, it should be remembered that these approaches were based on available information which is admittedly incomplete at this point. As expected, the responses are generally lacking in specific detail. Also, it might be expected that many organizations simply chose not to provide proprietary information at this early stage. Consequently, these responses should be viewed not as firm "proposals" but rather as descriptive narratives of potential approaches to a solution. Any of these responses could change significantly in response to a full RFP.

Also, because of the general nature of the specification, the organizations were only requested to provide "Rough-Order-of-Magnitude" (ROM) pricing. This pricing should therefore be viewed with caution. In addition, few organizations were comfortable in even providing ROM cost of a flight-rated model. Most proposed a phased approach, with the first phase being a feasibility study involving pre-prototype development. This stage would be used as a proof-of-concept and would develop necessary data and experience for a fully-operational breadboard.

The organizations who responded both with answers to our Questionnaire and a Technical Approach are presented in the following section (3.2.1). They are presented in alphabetical order. These organizations are:

Hoffrel Instruments	- South Norwalk, CT
IAPM	- Seattle, WA
Medasonics	- Fremont, CA
Medical Access. Inc.	- Trenton, NJ
Oxford/Sonicaid	- United Kingdom
Techno-Scientific	- Woodbridge, Ontario
Universal Sonics	- Mahwah, NJ

Organizations which did not return a complete response are presented in section 3.3, again in alphabetical order.

3.2.1 Hoffrel

3.2.1.1 The Approach

Hoffrel proposes a three phased approach to arrive at a working breadboard. This approach is based on modification and application of existing Hoffrel technologies. The Hoffrel strengths lie in 2D-imaging transducer design, mostly of the mechanical sector-scan variety.

Hoffrel proposes to utilize a Doppler flowmetry-based system in contrast to an "imaging" system, because a non-imaging system is more readily miniaturized. The Doppler system would most likely be a pulsed design with bubble detection based on analysis of the amplitude of the Doppler audio signal.

The first phase proposed by Hoffrel would be to adequately define the most advantageous anatomical site for monitoring of bubble activity, assuming that this is not directed by NASA staff. Hoffrel proposes a research program, most likely conducted in a 1G, altitude chamber environment, which would elicit air-embolism activity. Hoffrel proposes to utilize their transesophageal probe to closely monitor bubble activity within the heart. This approach gives very high resolution views of the heart (more especially the left heart) and would unequivocally detect bubble activity should it occur. Hoffrel is conducting research studies in conjunction with a number of scientists interested in air embolism detection and suggests that Dr. Charles Tegelar (Bowman-Gray School of Medicine) could serve as an experienced medical consultant if required in this initial phase.

The second phase of the program would be the modification of an existing precordial, sector-scan transducer (small enough to fit between a surgeon's fingers) for this application. The transducer presently operates at 5 MHz. Hoffrel would lower the operating frequency to achieve better penetration (due to less attenuation) and a somewhat divergent beam (assuming the same crystal diameter) which would make positioning less critical. Hoffrel would design a mechanical lock/attachment system to allow long-term placement on the astronaut's chest. Use of a sector-scan transducer would allow real-time adjustment of one axis of view, if necessary.

The third phase would be the design of the Doppler system. This would probably be based around an Application Specific IC (ASIC) for the analog processing and a CMOS microprocessor for control and data handling. At the end of this phase, a prototype of flight-size would be achieved.

Hoffrel estimates that these three phases would require 18 months of effort at a ROM price of \$306,000.

3.2.1.2 The Company

Hoffrel employs approximately 12 people and is based in South Norwalk, CT. Annual sales are approximately \$1M. The company specializes in duplex-scanner transducer design and currently markets over 80 models for use with their own equipment as well as that of other manufacturers. Hoffrel has been in the medical ultrasound marketplace for 28 years and has 46 years of cumulative engineering experience in design of medical ultrasound equipment. In addition, Hoffrel has designed equipment which is used specifically for air embolism detection in the medical market.

3.2.2 Institute of Applied Physiology and Medicine (IAPM)

3.2.2.1 The Approach

IAPM is proposing a system for realtime detection and quantification of air emboli in the pulmonary artery. IAPM considered five key elements in their response:

1. Doppler electronics.
In recognition of the Space Suit constraints, IAPM notes that flammability issues and static electricity issues must be recognized. For this reason, an air-backed transducer might have to be sealed if used in this environment. IAPM proposes to utilize a 2 - 2.5 MHz pulsed-Doppler system with a long range-gate. This approach is used in IAPM's current transcranial doppler design. The long range-gate approach is a compromise between a CW and a conventional pulsed system which provides both a strong signal and rejection of the strong echoes from many static targets (such as vessel and cardiac walls) in the beam path.
2. Precordial transducer array and control electronics.
IAPM proposes a transducer comprised of a 2-dimensional, planar array of approximately 9 to 16 ultrasound crystals operated in a pulsed mode. These individual crystals could be pulsed in synchrony, with continuous analysis of the return signal from each, or a single crystal could be selected and activated. A long-term coupling medium could be comprised of the conductive medium utilized for electrosurgical grounding pads. These pads adhere well to skin, yet do not extract significant amounts of body hair upon removal.
3. Pattern recognition algorithm for identification of pulmonary artery blood-flow.
IAPM expects that a predetermined location (1G experimentation) on the astronaut's chest would be used for the 0G application. Also determined in 1G would be the characteristic waveform of the astronaut's pulmonary artery bloodflow waveform. Using this predetermined waveform, IAPM would

utilize principal-component analysis to assure that the signal obtained in OG was from the correct location. IAPM staff has experience with using the principal-component technique in a non-invasive cardiac output monitor which transduced aortic bloodflow through the suprasternal notch.

4. Pattern recognition algorithm for bubble detection and quantification. IAPM has developed an algorithm for detection of air emboli and/or particulate reflectors in their Transcranial Doppler unit. They propose to adapt this algorithm to the in-suit, precordial bloodflow application. The algorithm is based on a matched filter approach (to the expected Doppler-spectral composition of air emboli) and detection of increased amplitude of the demodulated Doppler audio signal. IAPM proposes that the processing/detection system could be located in the ECLSS backpack assuming that through-connections are available from the interior to exterior of the Space Suit.
5. Recording and/or telemetry interface. If telemetry from the Space Suit is not available, an on-suit recording/memory device will be required. For a 6-hour mission, intermittent recording will probably be required to conserve power. Monitoring of 30-60 seconds every 15 minutes is proposed as a reasonable duty cycle. IAPM proposes that processed data could be multiplexed onto the low frequency end of the voice communication channel.

IAPM notes that the above development would require a three phase program with the approximate level of effort and cost as shown below:

1. Development of a system with no size constraints (and based on existing IAPM designs) which would be used for feasibility and proof-of-concept testing.
Effort: 11 person-months Cost: \$125,000
2. Design and fabrication of a breadboard of required size.
Effort: 34 person-months Cost: \$320,000
3. Development of the flight model.
Effort: not estimated Cost: not estimated

3.2.2.2 The Company

IAPM employs approximately 20 people and is located in Seattle, WA. The company has been in the medical ultrasound marketplace for approximately 20 years and has a cumulative 61 years of engineering experience in design of ultrasound equipment. IAPM performed feasibility studies for USAF/SAM on in-suit Decompression Sickness detection equipment in 1983-84. The company has experience in developing ultrasound equipment and algorithms for detection of air emboli in the medical environment. IAPM has conducted DCS research since 1971 in conjunction with Dr. Merrill Spencer. Dr. Spencer is an acknowledged leader in this field, having pioneered early efforts in the late 1960's.

3.2.3 Medasonics

3.2.3.1 The Approach

The Medasonics response was structured around three key topics:

1. Existing Technology.

Medasonics proposes to base a design on existing electronics which are used in their D-8 Versatone CW Doppler unit and Uniprobe system. The D-8 is a universal analyzer/back-end for several probe modules which mate with it. The Uniprobe is a handheld Doppler unit with electronics integrated into a module approximately 0.75" x 4" x 0.5". Medasonics also currently manufactures a 2.4 MHz transducer (approximately 1.3" diameter x 0.4" high) which is specifically designed for right atrial bubble detection. The transducer provides a very broad beam. The transducer is typically attached using adhesive tape and is quite stable after attachment in an operating room environment. Medasonics proposes to utilize these existing technologies to develop an early breadboard which could be used for preliminary testing.

Medasonics also proposes to develop a transducer which could be placed on the astronaut's neck for monitoring of carotid artery flow. This location would be used to detect arterial air emboli - which have much more serious sequelae than the venous emboli monitored in the right heart.

Medasonics has developed an approach for detection of motion artifact during ultrasound monitoring. This methodology is based on using Kynar piezoelectric film which can be integrated with the transducer housing. The output of this film can be used to indicate motion of respiratory or other origin. This system could be used to provide a motion alarm or a "squench" signal for the ultrasound output.

2. **Probe Development.**

Medasonics has experience with mechanically-manipulated, auto-aiming transducers in pulsed Transcranial Doppler systems. This technique did not work well without operator intervention. Based on these efforts, Medasonics feels that a multi-crystal, auto-aiming transducer approach will be poorly suited to a precordial monitoring application. A wide beam transducer is therefore proposed for the precordial position.

For the neck transducer, Medasonics proposes a linear array of crystals (not a phased array, however) which could span a small length across the expected carotid artery. Either an appropriate crystal could be chosen, or all crystals could be excited and the echoes analyzed for the desired flow signal. Medasonics feels that this particular application has a very high degree of commercialization potential for intraoperative use.

3. **Proposed Electronics**

For the initial development phase (see below) Medasonics proposes to utilize a modified Uniprobe electronics unit to drive both the precordial and neck transducers. RF multiplexing circuitry would be developed. A micro-processor would be used to perform transducer selection, spectrum analysis to determine bubble activity, and recognition of motion artifacts. Outputs would be the Doppler audio signals and a digital data stream for indicating bubble detection and transducer location.

Medasonics proposes the following phases and ROM costs (based on an approach which would potentially lead to a commercializable product):

1. **Concept Demonstration**

Modify existing systems (P81 and P94A probes, separate Uniprobe electronics for each probe, Cerebrovascular Diagnostic System - CDS) and use in altitude chamber tests. Develop algorithms for detection of bubbles and rejection of motion artifacts.

Cost: \$75,000

2. **Neck Probe Array and Electronics Breadboard**

Develop neck probe array with integrated Kynar motion-detection film. Develop multiplexed RF system to operate both precordial and neck probes with one Uniprobe-based electronics system. Develop compact breadboard version of embolism detection system.

Cost: \$250,000

3.2.3.2 The Company

Medasonics employs 150 people and is located in Fremont, CA. Medasonics has been in the medical ultrasound marketplace for 21 years and has 18 years of cumulative engineering experience. Medasonics has worked with NASA to deliver a Transcranial Doppler for simulated 0G aircraft testing. They have also been associated with flight hardware used in electromagnetic compatibility testing in the Skylab program (1972).

Medasonics markets Doppler ultrasound equipment designed specifically for air embolism detection in the right atrium/pulmonary artery during neurosurgical procedures. A TCD unit under development will include air/particle embolic event detection as a standard feature. A patent is pending for an air/particle embolism detector which minimizes the effect of motion artifacts. Much of Medasonics' equipment is battery operated.

3.2.4 Medical Accessories, Inc. (MAI)

3.2.4.1 The Approach

MAI currently has a design for a 5 MHz ultrasound system which was evaluated at NASA/JSC several years ago. MAI proposes to adapt this design for in-suit usage. Air embolism detection circuitry would be designed and integrated with the basic Doppler unit. MAI proposes to utilize rented spectrum analysis equipment in order to develop algorithms for detection of bubble activity in the Doppler signal. This bubble detection circuitry would automatically activate an internal recorder. MAI proposes to utilize manually operated switches for system duty cycle control.

ROM cost for development to the prototype stage: \$130,000.

3.2.4.2 The Company

MAI employs 40 people and is based in Trenton, NJ. The company has been in the medical ultrasound marketplace for 16 years and has 84 years of cumulative engineering experience. MAI has designed battery-operated ultrasound equipment for use in fetal heart rate monitoring and blood pressure monitoring equipment. Company strengths are in the areas of fetal heart rate monitoring, blood pressure monitoring, and air embolism detection.

MAI has previously designed a 2.5 MHz ultrasound unit which was used for intra-operative air embolism detection. This unit was marketed by Roche Medical Electronics as the Embosonde 2000.

3.2.5 Oxford/Sonicaid

3.2.5.1 The Approach

Oxford proposes to base an in-suit Doppler bubble detection system on an existing design for intraoperative use. This design, marketed as Sonicaid's model D206 Air Emboli Detector, utilizes a multi-crystal, wide-angle, low-profile transducer. Oxford would specifically address the issue of motion artifact rejection. Digital Signal Processing (DSP) techniques would be used to automate the detection of air bubble signatures in the Doppler signal. The existing D206 is battery powered and presently operates continuously for approximately 4 hours, although without an internal recorder. Design modifications could extend this battery life.

Oxford proposes that a modified D206 unit be designed as an essential precursor to development of a usable prototype. The modified D206 would be used in a proof-of-concept phase where testing would be performed in a simulated EVA scenario, ie., in an altitude chamber at 1G and/or the Water Evaluation Test Facility (WETF).

ROM Cost for development of modified D206: \$55,000. Time: 20 weeks

3.2.5.2 The Company

Oxford acquired the Sonicaid company in 1989 and thus assumed a line of medical ultrasound equipment. Oxford/Sonicaid employs 35 people and performs all R&D in the UK. Sonicaid has been in the medical ultrasound marketplace for 20 years and has 50 years of cumulative engineering experience. Sonicaid has developed ultrasound equipment which has been used specifically for air embolism detection. Key strengths are in the design of multi-crystal, wide-angle transducers and low noise analog signal processing circuitry.

3.2.6 Techno-Scientific, Inc. (TSI)

3.2.6.1 The Approach

TSI proposes to base their design for NASA on an existing TSI unit. This unit is the TSI DBM9008 ultrasound bubble detector. The basic DBM9008 is a 2.5 MHz, CW Doppler design and provides an audio output only. The unit operates for approximately 10 hrs. on a single 9V battery. The DBM9008 is designed for either precordial right heart or subclavian vein monitoring.

TSI provided, under previous contract to NASA, an "in-suit" version of this unit, designated as the DBM9008i. The DBM9008i utilizes a smaller transducer (approx. 2cm x 3cm) than the DBM9008. The DBM9008i also contains an integral tape recorder.

Formal documentation of the hardware evaluation is lacking at this time. Preliminary results indicate suboptimal performance due to limitations of either design or application.

TSI proposes to modify the DBM9008i transducer to achieve a lower profile. The CW approach will be retained as this is felt to provide more reliable bubble detection than a pulsed design.

For development of a prototype unit which would be used for feasibility testing the ROM cost is \$75,000 to \$120,000.

3.2.6.2 The Company

TSI employs five people and has been in the ultrasound marketplace for 10 years. The company has a cumulative 20 years of medical ultrasound design experience. TSI has experience in delivery of aerospace equipment to both NASA and Canadian organizations. Key TSI capabilities are in the areas of transducer design and Non-destructive Testing (NDT) utilizing ultrasound modalities.

3.2.7 Universal Sonics Corporation

3.2.7.1 The Approach

Universal proposes to utilize a CW Doppler unit with front-end electronics based on existing design technologies. A transducer comprised of an array of split-crystals is proposed, with each crystal being multiplexed sequentially. Each crystal output would be demodulated and its output either recorded or telemetered to a Doppler Processing Unit (DPU). This unit would not be located in the suit which would alleviate some of the problems and cost of miniaturizing a complex analysis system. The suit would contain only a Doppler Ultrasound Unit (DUU). The DUU would analyze the outputs from the various crystals and output a bubble signal while rejecting signals from body motion.

Universal proposes a 3 phased effort:

1. Feasibility Studies

This phase would aim at determining the optimum site for bubble detection and the optimal ultrasound frequency for transduction of the blood/bubble signal. This phase would also define the recording/storage requirements for the system. Finally, phase 1 would assess the feasibility of meeting the packaging and power requirements for in-suit usage.

Effort: 3 months

Cost: \$100,000

2. Breadboard Design

This stage would culminate with a working breadboard which would approximate the size and power requirements of the final design. The breadboard would be used for further ground-based testing.

Effort: 9 months

Cost: \$350,000

3. Flight-Model Design

Effort and Cost estimates not provided.

3.2.7.2 The Company

Universal Sonics employs 14 people and is located in Mahwah, NJ. The present company has been in the medical ultrasound marketplace for 6 years, although many of the engineers were previous employees of the Johnson & Johnson Ultrasound group. Universal has a cumulative 98 years of medical ultrasound design experience. They have 2 years of design experience of battery-operated equipment. Universal engineers have worked with RAFAEL (the Armament Development Authority of Israel) and have 10-20 years of experience in providing miniaturized, ruggedized flight equipment.

Universal currently provides custom ultrasound modules and assemblies to many of the large OEM ultrasound companies. Universal's expertise is in the areas of Doppler RF front ends, Doppler signal processing, and color flow-mapping modules. They have designed a compact, low-noise, CW/Pulsed Doppler operating over the 2 to 10 MHz range.

3.3 Organizations Supplying Other than Full Responses

Several other companies provided limited responses of varying degree to our Request to Industry. These companies were:

Applied Biometrics, Inc.	- Eden Prairie, MN
Advanced Technology Laboratories (ATL)	- Bothell, WA
Biosound, Inc.	- Indianapolis, IN
Carolina Medical Electronics	- King, NC
Diagnostic Ultrasound Corp.	- Kirkland, WA

Dymax Corp.	- Pittsburgh, PA
Eden Medical Electronics	- W. Germany
Electro-Diagnostic Instruments	- Burbank, CA
Elscent, Inc.	- Hackensack, NJ / Israel
Huntleigh Technology, Inc.	- Manalapan, NJ / UK
Kesa Corporation	- Santa Clara, CA
Koven & Associates (Hayashi Denki Co, Ltd. - HADECO)	- St. Louis, MO / Japan
Imex Medical Systems	- Golden, CO
Interspec, Inc.	- Ambler, PA
Life-Tech, Inc.	- Houston, TX
Millar Instruments, Inc.	- Houston, TX
Minntech Corp.	- Minneapolis, MN
Parks Medical Electronics, Inc.	- Aloha, OR
Scientronics Mfg. Co.	- St. James, NY
Tetrad Corp.	- Englewood, CO
Triton Technology, Inc.	- San Diego, CA
Vistec/ETRA	- Houston, TX
Zevex, Inc.	- Salt Lake City, UT

A brief summary of each of these company's response is presented in the following sections.

3.3.1 Applied Biometrics, Inc.

Applied Biometrics acknowledged receipt of our Request to Industry.

3.3.2 Advanced Technology Laboratories (ATL)

ATL acknowledged receipt of our Request to Industry and noted that this development was not within its strategic business interests.

3.3.3 Biosound, Inc.

Biosound acknowledged receipt of our Request to Industry.

3.3.4 Carolina Medical Electronics (CME)

CME acknowledged receipt of our Request to Industry and provided answers to our Questionnaire. CME has been in the medical ultrasound marketplace for 17 years and has 20 years of cumulative engineering experience. The company has no experience in design of battery-operated ultrasound equipment but does have experience in aerospace flight-rated equipment. In 1983, CME designed a flight ready electromagnetic blood flowmeter for use by Dr. Phillip Hutchins and NASA.

CME has experience in design of equipment specifically for circulating microbubble detection. In this regard, CME has received an NIH/SBIR grant in collaboration with Dr. David Stump and Dr. Charles Tegeler, both of Bowman Gray School of Medicine. CME has an active research program in air embolism detection and various CME staff and other researchers have published several articles in this field.

CME's primary expertise is in the area of electromagnetic blood flowmeters. CME now markets a color flow-mapping duplex Doppler system.

3.3.5 Diagnostic Ultrasound Corp. (DxU)

DxU responded to our Questionnaire. DxU has been in the ultrasound marketplace for 7 years and has a cumulative 14 years of ultrasound design experience. The company also has 14 years of experience in the design of battery-powered ultrasound equipment. DxU has assisted in the development of a catheter-based, air-emboli detection system.

DxU's strengths are in the area of small, hand-held, Doppler ultrasound devices. They have designed pulsed Doppler circuits in integrated/hybrid form which are used primarily in the Versadopp product line. A current 10

MHz design features an electronics module of approximately 0.5" x 0.2" x 1.8" and consumes only 15 mA at 5V.

3.3.6 Dymax Corp.

Dymax acknowledged our Request to Industry and responded to our Questionnaire. Dymax has been in the medical ultrasound marketplace for 12 years and has 10 years of cumulative engineering experience in the ultrasound field. Dymax developed a light-weight (7 lbs), battery-powered ultrasound scanner which has been marketed since 1986. Dymax is currently developing a new generation scanner. Dymax has several patents on single-moving part mechanized sector probes and on Tissue Signature Transceivers.

Dymax strengths are in the area of mechanical sector scanning probes with only a single moving part. Dymax is a leading OEM supplier of these probes. Dymax may be the only manufacturer of a battery-powered, sector scanner unit.

3.3.7 Eden Medical Electronics (EME)

EME acknowledged our Request to Industry and responded to the Questionnaire and provided a commentary on EME's background and experience in the air embolism field. EME has been in the medical ultrasound marketplace for 9 years and has 60 years of cumulative engineering experience in the design of medical ultrasound equipment. EME has 10 years experience in the design of battery-powered ultrasound devices.

EME has participated with NASA in the design/modification of Transcranial Doppler (TCD) Systems (the EME TC2-64). This is a 2 MHz, pulsed Doppler design. This system was flown on STS-29 (1989) and used in experiments conducted by Dr. Jim Bagian. EME has obtained a number of patents related to the mechanical aspects of transducer fixation.

Dr. Alec Eden, Chairman of EME's Scientific Advisory Board, has been a pioneer in both TCD research and intraoperative air-embolism research. Dr. Eden feels that EME could and would effectively respond to an RFP for the design of the in-suit Doppler system. In addition, based on his experience, he notes that a multi-crystal transducer design is unnecessarily complicated. Because of the envisioned size and power constraints, he would opt for a simpler design.

3.3.8 Electro-Diagnostic Instruments

Electro-Diagnostic Instruments acknowledged receipt of our Request to Industry.

3.3.9 Elscint, Inc.

Elscint acknowledged receipt of our Request to Industry and responded to our Questionnaire. Elscint has been in the medical ultrasound marketplace for 12 years and has 75 years of cumulative engineering ultrasound design experience. Elscint is a broad-based medical imaging company (MRI, Nuclear Medicine, Ultrasound) and markets heavily in Europe. In the ultrasound market, Elscint specializes in high-resolution, transvaginal imaging and has several patents in this area.

Elscint does not feel that the in-suit Doppler bubble detection system coincides with its product line and expertise.

3.3.10 Huntleigh Technology, Inc.

Huntleigh acknowledged receipt of our Request to Industry and responded by noting that they would be interested in responding to a future RFP.

3.3.11 Kesa Corporation

Kesa acknowledged receipt of our Request to Industry and responded to our Questionnaire. Kesa has been in the medical ultrasound marketplace for 10 years and has 15 years of cumulative engineering experience in this field. They have designed battery-powered equipment and have 5 years experience. Kesa has experience in both CW and pulsed Doppler designs.

Kesa strengths are in the areas of ultrasound transmitters/receivers, transducer design and interfacing, and magnetics design. Kesa currently has a battery-operated, single crystal CW Doppler prototype (patented) which has been used in animal labs for vessel location and blood flow evaluation. This design is the only known implementation of a single-crystal CW Doppler design capable of measuring both forward and reverse flow.

3.3.12 Koven & Associates (Hayashi Denki Co, Ltd. - HADECO)

Hayashi Denki (via Koven & Associates) acknowledged receipt of our Request to Industry and responded to our Questionnaire. Hadeco has been in the ultrasound marketplace for 35 years, has 250 years of cumulative engineering design experience and 250 cumulative years of battery-powered ultrasound system design experience.

Hadeco has experience in development of Doppler ultrasound equipment for deep sea microbubble detection (for animal testing only). Some of this technology and experience could be transferable to an in-suit Doppler system for NASA.

Hadeco strengths are in the area of CW blood flow detectors based on battery operation. Hadeco produces a line of instruments ranging from 2 to 10 MHz for blood flow velocity detection and blood flow volume measurement.

3.3.13 Imex Medical Systems

Imex acknowledged receipt of our Request to Industry.

3.3.14 Interspec, Inc.

Interspec acknowledged receipt of our Request to Industry.

3.3.15 Life-Tech, Inc.

Life-Tech acknowledged receipt of our Request to Industry.

3.3.16 Millar Instruments, Inc.

Millar acknowledged receipt of our Request to Industry.

3.3.17 Minntech Corp.

Minntech acknowledged receipt of our Request to Industry.

3.3.18 Parks Medical Electronics, Inc.

Parks acknowledged receipt of our Request to Industry and responded to our Questionnaire. Parks has been in the ultrasound marketplace for over 20 years and has over 30 years of cumulative engineering experience in the design of medical ultrasound experience. Parks also has over 30 years cumulative experience in the design of battery-powered ultrasound equipment.

The Parks model 915A-L has been used for monitoring microbubbles in intraoperative applications. Parks' strengths are in the area of low-current, battery-powered ultrasound equipment. Parks manufactures its own probes for all of its equipment.

3.3.19 Scientronics Mfg. Co.

Scientronics acknowledged receipt of our Request to Industry and responded to our Questionnaire. Scientronics had been in the ultrasound marketplace for 6 years. The company has 30 years of cumulative design experience of battery-powered ultrasound equipment. They have designed a probe for use in the detection of circulating microbubbles. Scientronics holds a patent for a 2 MHz ultrasound cuff probe.

3.3.20 Tetrad Corp.

Tetrad acknowledged receipt of our Request to Industry and noted that they would be interested in responding to an RFP. Tetrad is an independent design organization which designs custom ultrasound modules and equipment for OEM manufacturers.

3.3.21 Triton Technology, Inc.

Triton acknowledged receipt of our Request to Industry.

3.3.22 Vistec/ETRA

Vistec acknowledged receipt of our Request to Industry and responded to our Questionnaire. Vistec has been in the ultrasound marketplace for 22 years and has 45 years cumulative engineering experience in the design of medical ultrasound equipment. Vistec has 12 years experience in design of battery-powered ultrasound equipment.

Vistec has designed aerospace flight equipment including a visual display device to predict unconsciousness.

3.3.23 Zevex, Inc.

Zevex acknowledged receipt of our Request to Industry and responded to our Questionnaire. Zevex has been in the medical ultrasound marketplace for 5 years and has 75 cumulative years of engineering experience in this field. Zevex has experience with flight equipment, having supplied ultrasonic air-bubble detection systems (for flowing fluids) on the Space Shuttle. Zevex's major strengths are in the design of ultrasound applications involving air detection in fluids.

3.4 Discussion of Organizations and Approaches

As expected (and desired), our Request to Industry elicited a broad range of responses from interested organizations. This range of responses has been helpful in assessing the state-of-the-art in this field and understanding the hurdles which must be overcome for a successful development.

The previous section has presented our summary of the responses from the listed organizations. Please see the Appendix for copies of the unabridged responses from each organization. In this section, we discuss the various approaches and organizations.

3.4.1 Objective Organizational Data

For the organizations providing either full or partial responses, the table on the following page summarizes each organization's experience, capabilities, and resources.

ORGANIZATIONAL DATA							
NAME	A	B	C	D	E	F	G
Carolina Medical Electronics	17	20	N	-	Y	Y	N
Diagnostic Ultrasound Corp.	7	14	Y	14	N	Y	N
Dymax Corp.	12	10	Y	10	N	N	N
Eden Medical Electronics	9	60	Y	10	Y	Y	N
Elscint	12	75	N	-	N	N	N
Hoffrel	28	46	N	-	N	Y	Y
IAPM	20	52	Y	37	Y	Y	Y
Kesa Corp.	10	15	Y	5	N	N	N
Koven and Associates (Hadeco)	35	250	Y	250	N	Y	N
Medasonics	21	18	Y	3	Y	Y	Y
Medical Accessories, Inc.	16	84	Y	84	Y	Y	Y
Oxford/Sonicaid	20	50	Y	20	N	Y	Y
Parks Medical Electronics	20+	30+	Y	30+	N	Y	N
Scientronics Manuf. Co.	6	30	Y	30	N	Y	N
Techno Scientific, Inc.	10	20	Y	3	Y	Y	Y
Universal Sonics	6	98	Y	2	Y	Y	Y
Vistec/ETRA	22	45	Y	12	Y	Y	N
Zevex	5	75	N	-	Y	Y	N

QUESTION CODING

- A - How many years has the organization been in the ultrasound marketplace?
- B - How many cumulative engineering person-years of experience does the current staff have in designing medical ultrasound equipment?
- C - Does the organization have experience in design of battery-operated, medical, ultrasound equipment?
- D - If yes to (C), how many cumulative engineering person-years?
- E - Does the organization have experience in design of flight equipment?
- F - Does the organization have experience in design of ultrasound equipment specifically for circulating microbubble detection?
- G - Did the organization submit a "Description of Technical Approach"?

To derive a somewhat objective evaluation of the matrix above, we have attempted to calculate a "score" for each of the eighteen organizations. In order to do this, we first calculated a weighting factor for the Yes/No answers. To derive the value of the weighting factor, we calculated the mean of all numerical entries in the table, ie., columns A, B, and D. The mean of all these entries was 33. Using this weight, "Y" answers were calculated as 33, and "N" answers as 0.

Secondly, numerical data (Columns A, B, and D) were ranked into High (=33 points), Moderate (=16.5 points), and Low (=0 points) ranges. To assign values, each column was sorted in numerical order. Then the eighteen organizations were divided into three groups. In cases of two organizations with equal scores falling across a group boundary, both organizations were assigned to the higher group.

The results of this "scoring" are shown in the following table. The scores indicate an approximate four to one range from highest to lowest.

While this approach obviously cannot be defended in a rigorous manner, it does at least provide a first attempt at evaluating these organizations in areas which will be important to this development.

Importantly, it should be noted that the rankings rely heavily on a "self-assessment" by each manufacturer. For this reason, we do not place too heavy an emphasis on these results. In particular, "outlying" values, as in any data set, should be examined critically.

ORGANIZATIONAL RANKINGS	
NAME	RELATIVE "SCORE"
Inst. of Applied Physiology and Medicine	214
Medical Accessories, Inc.	214
Oxford/Sonicaid	181
Medasonics	181
Koven/Hadeco	165
Vistec	165
Universal Sonics	165
Techno Scientific Inc.	165
Parks Medical Electronics	148
Eden Medical Electronics	148
Hoffrel Instruments	115
Scientronics Manuf. Co.	115
Zevex	99
Diagnostic Ultrasound Corp.	82
Carolina Medical Electronics	82
Kesa Corp.	66
Dymax	66
Elscint	50

3.4.2 Subjective Evaluation of Technical Approaches

Most organizations have proposed a phased approach to a final, flight-rated assembly. In addition, most organizations have recognized the need for additional basic research in the areas of preferred monitoring site, transducer design, and bubble detection algorithm development.

The organizations with current commercial products which are being used in air embolism detection are of particular interest in the current development. An organization with relevant experience in this field will be most likely to have a more complete appreciation for the potential problems. These organizations are listed in the previous table with an indication of "Y" in column F.

Overall, it is difficult to judge the submitted Technical Approaches because of the general nature of their content. This does not reflect negatively on any particular organization and was to be expected due to the incomplete nature of the specifications which we supplied. Moreover, it is possible that some organizations chose to withhold their best ideas in this current "open" environment where any response could conceivably be available to a future competitor.

The key determinants of success for this development can be categorized in the following areas:

- Applicable Experience
- Understanding of the Problem
- Expertise, demonstrated
- Understanding of Flight Qualification Requirements
- Willingness to Cooperate

Based on the responses submitted, conversations with key corporate personnel, and personal experience and observations, we felt that some organizations appeared to display a more complete understanding of the field and of the potential problems in this development. After evaluating each organization, albeit subjectively, in the areas listed above, several organizations again appear to stand out. These organizations were Hoffrel, IAPM, and Medasonics.

Beyond these three however, we feel that most organizations which market a product for air embolism detection could confidently respond to an RFP. From the table above, fifteen organizations responded that they currently manufactured such a product. It is an encouraging prospect that this much basic expertise is available.

It should also be noted that many other organizations could supply a more complete proposal in a competitive RFP environment. It is LSR's assessment that, based on personal conversations and knowledge of these organizations, there are other organizations capable of responding who may not have done so in this open environment. Among these organizations are Eden Medical Electronics, Parks Medical Electronics, and Tetrad.

In summary, the Request to Industry has served its purpose of a) acquiring data on the experience and capabilities of many ultrasound manufacturing organizations and, b) eliciting a number of technical discussions aimed at providing an in-suit ultrasound air embolism detection system.

4.0 SUMMARY AND RECOMMENDATIONS

We have developed a thorough understanding of the field of circulating air embolism research and, in particular, its detection and quantification with ultrasound techniques. We have reviewed the medical literature, talked with experts in the field, contacted numerous organizations capable of providing hardware for measuring in-suit air emboli during EVA, observed ongoing air embolism research at NASA/JSC altitude chambers, and surveyed many databases for technology relevant to the proposed development. This section presents our summary and recommendations base on the best available information.

4.1 Organizational Groupings

We have identified several organizations with high potential for providing quality hardware. Although extremely difficult to judge based upon the limited information which we have from these vendors, we feel that several organizations which responded to our Request to Industry fall into a group which we could categorize as "most likely" to be able to produce a flight-rated, in-suit ultrasound bubble detector. These organizations, in our judgment, are Hoffrel, LAPM, and Medasonics.

There are several other organizations that market ultrasonic bubble detection devices or systems. These organizations, in addition to the four listed above, are Carolina Medical Electronics, Diagnostic Ultrasound Corp., Eden Medical Electronics, Koven (Hadeco), MAI, Oxford/Sonicaid, Parks Medical Electronics, Scientronics, Techno Scientific, and Vistec. With this experience, many of these companies have potential for excellent work in this field.

There is a third group of organizations for which we have very little information. These organizations either gave little or no response to our request. In the event that a competitive bid is solicited, it is possible that a significant proposal could come from this group.

4.2 Key Issues for Future Development

As we have found in our literature searches, seen in altitude chamber testing at NASA, and indicated in the responses from industry, a number of key issues are yet to be resolved in this development. Unqualified answers to the following questions are critical to program success.

1. What is the best/preferred anatomical site for bubble observation? Should only venous circulation be monitored or should arterial circulation also be considered?
2. Is continuous monitoring required? If intermittent monitoring is acceptable, what is an acceptable duty cycle?
3. How difficult is it to acquire and maintain a quality signal from the preferred site during moderate body movement over extended periods of time?
4. Is Doppler ultrasound or Echo ultrasound most likely to succeed in providing definitive recognition of circulating microbubbles?
5. Is pulsed or continuous wave Doppler the best modality?
6. Is automated, real-time bubble detection required? If so, can the detection system be located off-suit?
7. Is telemetry available from the Space Suit and/or is an in-suit recorder and/or memory system required?
8. What Space Suit constraints (voltage, interfaces, O₂ environment) will have the greatest impact on the in-suit design?

The following section outlines our recommendations for a rational approach for resolving these questions.

4.3 Recommendations for Next Phase

As determined from responses to the Request to Industry, as well as LSR's experience in program development, there are a number of key steps which must be accomplished in order to successfully implement an in-suit Doppler bubble detection system. Some of these steps are obviously the responsibility of NASA Science, while others fall into the area of Engineering.

It is our observation that a significant amount of basic research should be completed before flight hardware should be requisitioned. At this time, it is premature to expend large amounts of funds for customized hardware. It is our recommendation that a well-planned program of laboratory testing, utilizing off-the-shelf equipment with limited modifications, be undertaken. This is the "Feasibility Phase" and would, at a minimum,

endeavor to answer the engineering questions outlined below. Following a successful Feasibility Phase, the Breadboard and Flight Equipment Phases logically follow.

I. Feasibility Phase

- a. Select a plurality of vendors to provide modified off-the-shelf equipment for laboratory experiments.
- b. Determine anatomical site(s) for measurement
- c. Determine most stable transducer/probe assembly design
- d. Determine ultrasound modality for best reliability/signal quality
- e. Determine if automated bubble detection is feasible/desirable.
- f. Determine data storage requirements

II. Breadboard Phase

- g. Design breadboard
- h. Tests in altitude chamber/WETF
- i. Modify breadboard, if required

III. Flight Model Phase

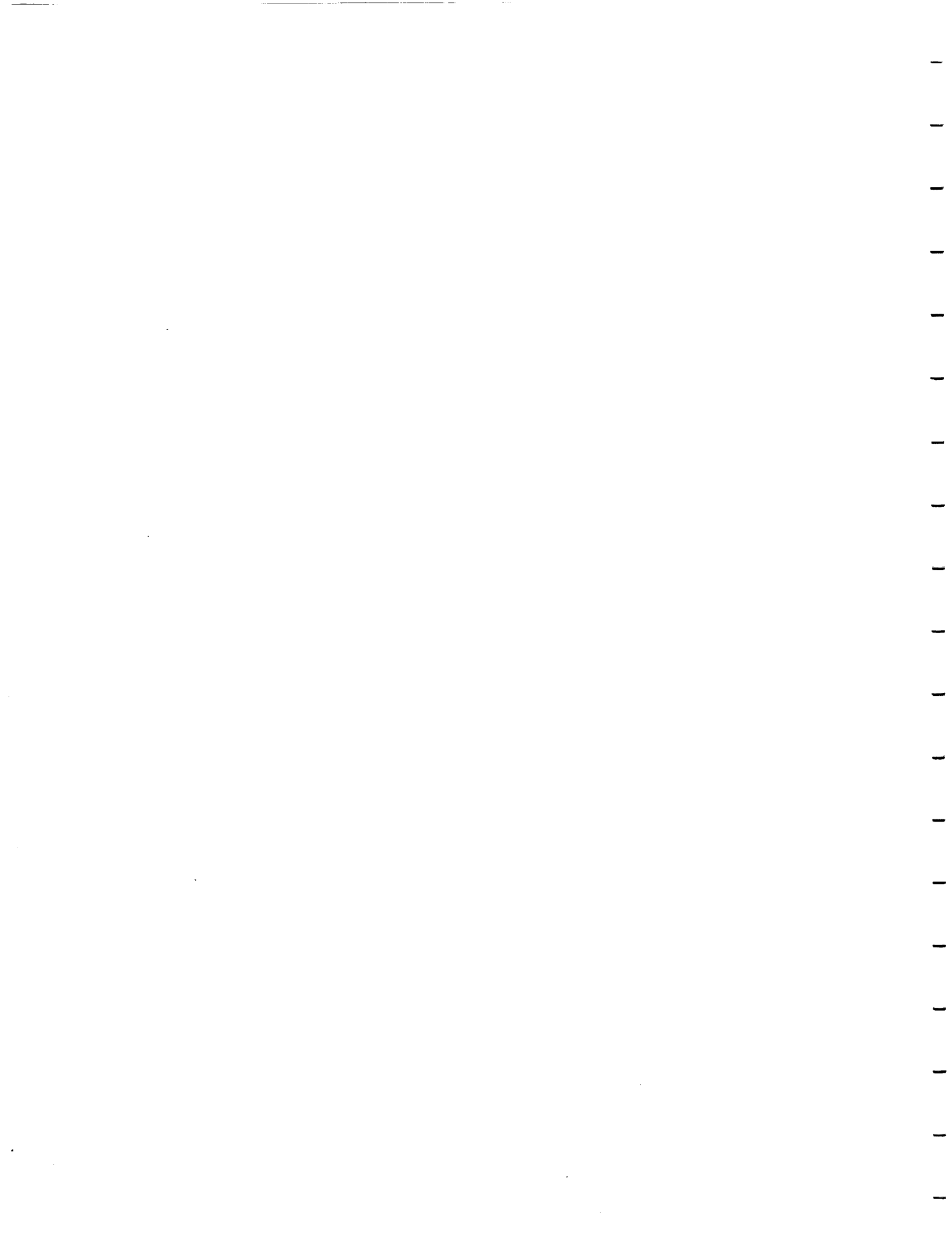
- j. Design flight model
- k. Tests in altitude chamber/WETF
- l. Flight Qualification

To proceed with the Phase I Feasibility Testing, we recommend that organizations supply modified off-the-shelf hardware which is capable of meeting certain minimal specifications. Within budget constraints, NASA should consider acquisition of hardware from more than one vendor. This would enable the utilization and evaluation of a range of approaches. This hardware would then be evaluated in a laboratory setting by highly-trained personnel, under well-controlled conditions, with a protocol designed to address the critical issues itemized under the Feasibility Phase.



5.0 APPENDICES

- Appendix A - References
- Appendix B - Definitions of Terms
- Appendix C - Request to Industry
- Appendix D - Sample Database Search
- Appendix E - List of Ultrasound Manufacturing/R&D Organizations
- Appendix F - Responses to Request to Industry
- Appendix G - Sample Ultrasound Transducer Patent (Abstract)
- Appendix H - Sample Manufacturers' Literature



APPENDIX A

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APPENDIX B

Definitions of Terms



Air emboli - A small circulating bubble of gas which, when spontaneously occurring in the human body, is probably in the micron-size class and consisting largely of nitrogen gas. The majority of air emboli are harmlessly filtered by the lungs.

Aorta - The main blood vessel carrying oxygenated blood away from the heart to the body tissues.

Arterial circulation - The blood vessels which carry blood away from the heart. This may be either oxygenated blood (to the body tissues via the Aorta) or deoxygenated blood (to the lungs via the Pulmonary Artery). Normal pressures range from 140 to 10 mmHg.

Backscatter - Scattering of ultrasound at an angle of 180 degrees to the beam direction. Generally created by scatterers with dimensions similar to the wavelength of the ultrasound wave.

Color Flow-mapping Doppler system - A duplex system capable of displaying a sector-scan image and a superimposed color-coded flow velocity created by a multi-gated pulsed Doppler. Both are typically shown in real time at 15 -20 frames/sec.

Continuous wave (CW) ultrasound - A system employing an uninterrupted transmission of ultrasound energy accompanied by a continuous reception of reflected ultrasound, normally by separate, isolated crystals. The sampling region is fixed and determined by the intersection of the transmitting and receiving beams. Spatial resolution is limited in spite of improved Signal-to-Noise ratios and maximal temporal and velocity resolution.

Decompression sickness (DCS) - The classical term applied to the spectrum of symptoms elicited when gas-laden tissues are brought to a lowered atmospheric pressure. Clinical manifestations may range from mild joint-awareness, through debilitating pain, to unconsciousness and death.

Doppler System - An ultrasound system capable of transducing blood flow velocity information based upon the Doppler principle whereby ultrasound reflected from a moving target is shifted in frequency (relative to the incident frequency).

Duplex Scanner - An ultrasound system capable of displaying both imaging ("echo") and blood velocity ("Doppler") information.

Fast Fourier Transform - A numerical algorithm to compute the frequency components present in a function. The FFT produces an estimate of the relative amplitude of each frequency component and is a standard method in Doppler signal processing.

Formed-element emboli - In contrast to an air-embolus, this is a small circulating mass which, when spontaneously occurring in the human body, is probably a solid component. As with air emboli, formed-element emboli are filtered by the lungs on the venous side. Arterial formed-element emboli are much more dangerous and can occlude blood flow to regions of the brain, thus creating "strokes."

Gas nucleation - Formation and growth of gas phase regions in a supersaturated liquid medium.

Imaging System - An ultrasound system capable of displaying the amplitude of the signal reflected from interior reflectors. The ultrasound beam is usually swept across an arc (either mechanically by a motor-driven crystal assembly or electrically with a phased array) at a rapid rate (12-42 frames/sec). The image is derived by displaying the amplitude of the returned signal in a gray scale. (The simplest "image" is one-dimensional and consists of an amplitude versus time display - known as an "M-mode".)

Intraoperative - Pertaining to procedures performed during surgery.

Precordial - Pertaining to the area "before" the heart or, in the ultrasound context, the external chest wall over the heart but left of the sternum.

Pulmonary artery - The blood vessel which carries deoxygenated blood from the right ventricle of the heart to the lungs for oxygen and carbon dioxide transfer. It is generally 5-8 centimeters long and 2 centimeters in diameter before it bifurcates into its left and right branches to the respective lungs.

Pulsed ultrasound - A system employing a single piezoelectric crystal for both transmitting and receiving the ultrasound energy. The crystal is time multiplexed between a relatively short transmitted signal (typically 1 - 100 microseconds) and a much longer receiving period (typically 1 - 100 milliseconds). The sampling region (sample volume) can be electrically controlled and placed anywhere along the transducer beam for optimal range/spatial resolution at the expense of temporal and velocity resolution.

Range Gate - In a pulsed Doppler system, the period of time after the transmit pulse during which the receiver is enabled and the reflected signal is captured. Varying the delay between the transmitted pulse and the opening of the range gate allows reflected signals from varying depths to be analyzed.

Right ventricular outflow tract (RVOT) - The flow channel between the heart's right ventricle and the pulmonary valve and artery. It is generally 3-5 centimeters long and 2 centimeters in diameter.

Sample Volume - The region in the ultrasound beam from which the Doppler signals are detected.

Saturation signal - Large value of the Doppler signal that cannot be accommodated by the receiver. Often occurs in bubble detection by Doppler.

Transcranial Doppler (TCD) - An ultrasound system designed specifically for transduction of blood flow velocity signals from within the head. Because the ultrasound energy must transverse bone, a significant impediment to ultrasound, TCD systems typically utilize much higher transmitted energy levels (adjustable) than cardiovascular systems.

Transducer (ultrasound) - A piezoelectric crystal (rigid) or polymer (flexible) capable of converting sound energy to electrical energy and vice versa. Transducers for medical applications typically operate in the 1 - 20 MHz band of frequencies and can be placed in a variety of configurations for non-invasive, intracavity, intraluminal, or transluminal applications.

Ultrasound - Pressure variations at a frequency well above the range of hearing. In medical applications, frequencies generally range from 1 to 20 MHz. Energy levels generally do not exceed 50 mW/cm².

Venous circulation - The blood vessels which carry blood toward the heart. This may be either deoxygenated blood (from the body tissues via the Vena Cava) or oxygenated blood (from the lungs via the Pulmonary Vein). Normal pressures range from -5 to 10 mmHg. The venous circulation is most susceptible to decompression air emboli.

APPENDIX C

Request to Industry



LSR

INCORPORATED

October 16, 1991

Dear Sir or Madam:

LSR is conducting a survey of organizations for NASA and GE Government Services to determine potential concepts and manufacturers of a customized medical ultrasound device for measurement of air emboli. The device is described in the following pages.

Your organization's response is very important to us. We wish to identify all interested parties. *Please note the due dates on the 3 items listed on the next page.* Your timely response will insure that your organization is represented in our final report to NASA/GE.

If you do not plan to participate, would you please so indicate by checking the box at the bottom of the Questionnaire and returning it to me?

Thank you for taking the time to respond to this request. If you need additional information, please do not hesitate to call either me at 505-262-7749 or Dick Greene, PhD, at 505-262-7155. We will be glad to help.

Yours sincerely,

Jerry G. Davis
Vice-President

2441 Ridgecrest, S.E.
Albuquerque, New Mexico 87108
(505) 262-7749
Fax: (505) 262-7616

"In-Suit Ultrasonic Bubble Detector for EVA"

BACKGROUND INFORMATION and INSTRUCTIONS

Astronauts often perform tasks which require Extravehicular Activity (EVA). During an EVA, an astronaut wears a space suit which maintains an internal pressure of only 4 to 5 psia in order to maximize suit flexibility. At this reduced pressure, the potential for formation and circulation of gas microbubbles in the astronaut's bloodstream is a concern. In its early stages, this phenomenon is sometimes associated with joint discomfort or pain (commonly called "the bends"). Although never observed in the limited number of EVAs by NASA astronauts, circulating microbubbles have the potential for serious clinical sequelae.

Based on research experience, NASA is considering the development of a battery-powered, ultrasound-based system which can be worn by an astronaut inside a space suit and can continuously monitor bubble activity in the astronaut's blood. Under contract to NASA/GE Government Services, LSR is performing a survey to identify potential methodologies and manufacturers of such a custom system. The present LSR effort does not contain funding for a development program.

We are requesting three (3) items from you:

1. **Completed Questionnaire - Due Oct. 25, 1991.** Included with this package is a questionnaire which will help us develop a more thorough description of your company. Please answer the questions as accurately as possible and include additional explanatory text, if necessary.
2. **Corporate/Product Description - Due Oct. 25, 1991.** Please send a set of sales/marketing literature which describes your organization's products, capabilities, and experience.
3. **Description of Technical Approach - Due Nov. 1, 1991.** Also accompanying this document is a brief description of the "requirements" for the system. We would like for you to give us a response to the stated requirements, realizing that the system is still in its conceptual stage. We are not requesting a detailed proposal, but rather a short document (a "white paper") which describes your approach to this system and addresses the major technological issues of this task. Also, include a rough-order-of-magnitude price to develop an operational breadboard of the system.

***** Do not include any proprietary or confidential information. *****

Mail to: Jerry G. Davis, VP
LSR, Inc.
2441 Ridgecrest, SE
Albuquerque, NM 87108

Phone: 505-262-7749
FAX: 505-262-7616

REQUIREMENTS

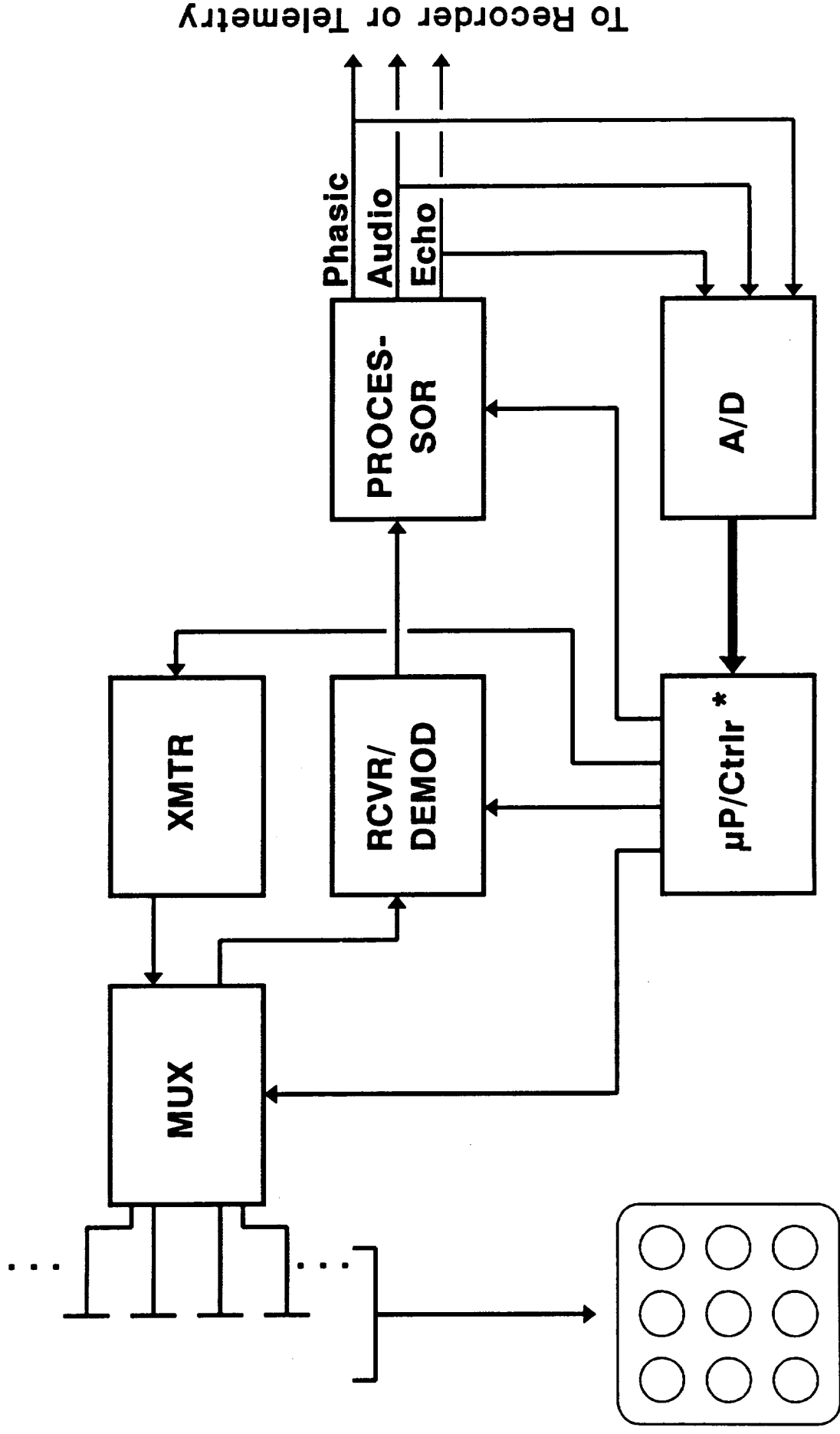
This document is a broad definition of a small, battery-powered, ultrasound-based instrument capable of monitoring micron-sized bubble activity in the pulmonary artery bloodflow of an astronaut in a space suit. Other monitoring sites may also be considered. Once configured, the instrument must operate unattended during Extravehicular Activity.

In one potential configuration, the system would consist of a low-profile transducer located on the astronaut's chest (worn under a cooling garment made of a "spandex-like" material with imbedded tubing for circulating water). All processing electronics would also be located inside the space suit. The output signal(s) may either be recorded on a small recording device/module mounted inside the space suit or telemetered from the space suit.

A concept utilizing a multiple-crystal transducer is shown in simplified form on the attached drawing. This concept could potentially track a moving vessel. However, this is representative only, and any/all other approaches are welcome and encouraged.

1. Transducer-to-Site Interface: self-attaching/adhering. Stable and continuously operable without operator manipulation after initial attachment.
2. Artifact Rejection: Capable of continuously monitoring bubble activity with little artifact during slow upper body movements.
3. Dynamic Range: Sufficient dynamic range to detect and record bubble echoes without saturation or distortion.
4. Transducer Size: Low profile, comfortably worn under the cooling garment.
5. Power: Battery-powered, minimum 6 hour capacity
6. Weight: Breadboard < 3 lb
(Flight model weight less than 0.5 lb)
7. Volume: Breadboard < 50 in³
(Flight model volume less than 5 in³)
8. Operating temperature: 60 - 100 °F (15 - 38 °C)
9. Operating atmosphere: 100% O₂ @ 4 psia

Pulsed. Multi-element Concept



* "Smart" controller selects transducer crystal and adjusts Sample Volume for "best" output.

QUESTIONNAIRE

Your name: _____ Telephone #: _____

Your organization: _____

1. How many years has your organization been in the ultrasound marketplace? _____
2. How many cumulative engineering person-years of experience does your current staff have in design of medical ultrasound equipment? _____
3. Does your organization have experience in design of battery-operated, medical, ultrasound equipment (Y/N)? _____ If yes, approximately how many cumulative engineering person-years? _____
4. Does your organization have experience in design of flight equipment (Y/N)? _____
If yes, please explain: _____
5. Does your organization have experience in design of ultrasound equipment specifically for circulating microbubble detection (Y/N)? _____ If yes, please explain: _____
6. What are your organization's unique strengths in the design of ultrasound equipment? _____
7. What patents or intellectual property does your organization hold which could be relevant to this project? _____
8. Will your organization be submitting a "Description of Technical Approach" by Friday, November 1, 1991 (Y/N)? _____

☐

My organization chooses not to submit a response to this request.



APPENDIX D

Sample Database Search

SEARCH TERMS: embolism.mj. and ultrasonography.mj. and air
--> 21 DOCUMENTS FOUND

1

R021 Links Available

AN 91165125. 91063.

AU Russell-D. Madden-K-P. Clark-W-M. Sandset-P-M. Zivin-J-A.

IN Department of Neurosciences, University of California, San Diego, La Jolla.

TI Detection of arterial emboli using Doppler ultrasound in rabbits.

SO Stroke. 1991 Feb. 22(2). P 253-8.

JT STROKE.

PT JOURNAL ARTICLE (ART).

LG English (EN).

AB The purpose of this study was to develop an animal model that could be used to test the ability of Doppler ultrasound to detect arterial emboli composed of materials that are often involved in cerebral emboli. Emboli introduced into the rabbit aorta via the left renal artery consisted of clotted whole blood, platelets, atheromatous material, fat, or *air.* The ultrasound examination was carried out continuously during the studies using a multifrequency transcranial Doppler apparatus with a 2-MHz probe, a sample volume of 15 mm, at a depth of 15 mm. The intensity of the Doppler spectrum was measured and displayed as a 15-shade color scale, each shade representing a 3-dB difference. The diameter of the aorta at the site of the ultrasound examination was similar to the diameter of the middle cerebral artery in humans. All 125 emboli introduced were clearly detected because they caused a Doppler signal at least 15 dB greater than that of the surrounding blood. These results show that the potential for emboli detection using Doppler ultrasound in the clinical situation is now considerable. Author-abstract.

MJ *CEREBRAL-EMBOLISM-AND-THROMBOSIS:* *ultrasonography* (us).

MN ANIMAL. BLOOD-FLOW-VELOCITY. *CEREBRAL-EMBOLISM-AND-THROMBOSIS:* physiopathology (pp). CEREBROVASCULAR-CIRCULATION. HUMAN. RABBITS. SUPPORT-NON-U-S-GOVT. SUPPORT-U-S-GOVT-P-H-S.

SB Priority Journals (M).

YR 1991.

IS 0039-2499. V2J.

CP UNITED-STATES (Z1.107.567.875).

IM 9106.

ND ENTRY DATE: 910418.

NO NS23814.

2

AN 91138424. 91055.

AU Marcus-R-H. Weinert-L. Neumann-A. Borow-K-M. Lang-R-M.

IN Department of Medicine, University of Chicago Medical Center 60637.

TI Venous *air* *embolism.* Diagnosis by spontaneous right-sided contrast echocardiography.

SO Chest. 1991 Mar. 99(3). P 784-5.

JT CHEST.

PT JOURNAL ARTICLE (ART).

LG English (EN).

AB This report describes the definitive diagnosis of venous *air-embolism* by documentation of spontaneous echo contrast in the right cardiac chambers following removal of a jugular venous catheter in a patient with hepatic failure. This complication was potentiated by the presence of concurrent hepatic coagulopathy which prejudiced effective hemostasis at the central venous puncture site. Author-abstract.

MJ ECHOCARDIOGRAPHY. *EMBOLISM-AIR:* *ultrasonography* (us).
MN CASE-REPORT. CATHETERIZATION-CENTRAL-VEIN: adverse-effects (ae).
FEMALE. HUMAN. JUGULAR-VEINS. MIDDLE-AGE.
SB Abridged Index Medicus Journals (A). Priority Journals (M). Cancer
Journals (X).
YR 1991.
IS 0012-3692. D1C.
CP UNITED-STATES (Z1.107.567.875).
IM 9105.
ND ENTRY DATE: 910328.

3

AN 91122522. 91053.
AU Bodewes-H-W. Puyllaert-J-B.
IN Department of Radiology, Westeinde Hospital, The Hague, The
Netherlands.
TI Ultrasound in detection of portal venous gas in adults.
SO Gastrointest-Radiol. 1991 Winter. 16(1). P 35-7.
JT GASTROINTESTINAL RADIOLOGY.
PT JOURNAL ARTICLE (ART).
LG English (EN).
AB Three patients with sonographically demonstrated portal venous gas
are presented. Two patients were also studied using computed
tomography (CT). Both techniques had superior sensitivity compared
to plain radiographs. Scattered echogenic patches in the liver
parenchyma, and centrifugal flow of echogenic patches in the portal
vein and its branches, are typical ultrasound findings of portal vein
gas. Evaluation of ultrasound findings and coordination with
clinical history differentiate portal vein gas from biliary gas.
Author-abstract.
MJ *EMBOLISM-AIR:* *ultrasonography* (us). PORTAL-VEIN: *ultrasonography*
(us).
MN AGED. AGED-80-AND-OVER. CASE-REPORT. *EMBOLISM-AIR:* radiography
(ra). FEMALE. HUMAN. LIVER: *ultrasonography* (us). PORTAL-VEIN:
radiography (ra). TOMOGRAPHY-X-RAY-COMPUTED.
SB Priority Journals (M).
YR 1991.
IS 0364-2356. FGZ.
CP UNITED-STATES (Z1.107.567.875).
IM 9105.
ND ENTRY DATE: 910308.

4

AN 91121831. 91053.
AU Clayton-R-H. Pearson-D-T. Murray-A.
IN Regional Medical Physics Department, Freeman Hospital, Newcastle upon
Tyne, UK.
TI Clinical comparison of two devices for detection of microemboli
during cardiopulmonary bypass.
SO Clin-Phys-Physiol-Meas. 1990 Nov. 11(4). P 327-32.
JT CLINICAL PHYSICS AND PHYSIOLOGICAL MEASUREMENT.
PT JOURNAL ARTICLE (ART).
LG English (EN).
AB Detection of gaseous microemboli during cardiopulmonary bypass
procedures is important for the clinical evaluation of equipment such
as oxygenators and cardiectomy reservoirs. Comparison of published
data can be difficult if different detectors are used. Two devices
reported in the literature, the Technique Laboratories TM-8 and the
Hatteland BD-100, are compared during clinical procedures. The
relationship between the outputs of these devices was linear over two

ranges, the difference in output amounted to a standard deviation of 11% in the lower range and 38% in the upper range. Author-abstract.
MJ CARDIOPULMONARY-BYPASS. *EMBOLISM-AIR:* *ultrasonography* (us).
MN COMPARATIVE-STUDY. *EMBOLISM-AIR:* etiology (et). HUMAN.
OXYGENATORS. SUPPORT-NON-U-S-GOVT. *ULTRASONOGRAPHY:* instrumentation (is).
SB Priority Journals (M).
YR 1990.
IS 0143-0815. DKB.
CP ENGLAND (Z1.542.363.300).
IM 9105.
ND ENTRY DATE: 910314.

5

R021 Links Available

AN 91112878. 91051.

AU van-der-Linden-J. Casimir-Ahn-H.

IN Department of Anesthesia and Intensive Care, University Hospital, Uppsala, Sweden.

TI When do cerebral emboli appear during open heart operations? A transcranial Doppler study.

SO Ann-Thorac-Surg. 1991 Feb. 51(2). P 237-41.

JT ANNALS OF THORACIC SURGERY.

PT JOURNAL ARTICLE (ART).

LG English (EN).

AB The transcranial Doppler technique enabled the detection of cerebral *air* emboli in 10 of 10 patients during open-heart valve operations despite standard deairing procedures. With this technique, the occurrence of emboli in the right middle cerebral artery was followed continuously in patients undergoing aortic or mitral valve replacement. Membrane oxygenators were used. Scattered emboli were observed during the insertion of the aortic cannula, at the start of cardiopulmonary bypass, and after the declamping of the aorta with the heart beating while empty. During the period of aortic cross-clamping, no emboli were detected. Despite careful deairing procedures, the recordings indicated a large amount of emboli during filling of the empty beating heart in all 10 patients. Thus, this study indicates that cerebral emboli in open heart procedures are most likely to occur during the redistribution of blood from the heart-lung machine to the patient when the heart is beginning to eject actively, despite careful standard deairing procedures. Meticulous deairing before declamping the aorta is strongly advocated. In addition, a short period of filling of the beating heart before final closure of the aortic incision or vent may decrease the incidence of cerebral emboli. A concomitant reduction in cerebral blood flow by hyperventilation or anesthetics or both during filling of the empty beating heart may also be beneficial. Author-abstract.

MJ *CEREBRAL-EMBOLISM-AND-THROMBOSIS:* *ultrasonography* (us).
EMBOLISM-AIR: *ultrasonography* (us). HEART-SURGERY: adverse-effects (ae).

MN AORTIC-VALVE: surgery (su). CEREBRAL-ANGIOGRAPHY.

CEREBRAL-EMBOLISM-AND-THROMBOSIS: etiology (et), radiography (ra).

EMBOLISM-AIR: etiology (et), radiography (ra). HUMAN. MITRAL-VALVE: surgery (su). MONITORING-PHYSIOLOGIC. SUPPORT-NON-U-S-GOVT.

TIME-FACTORS. TOMOGRAPHY-X-RAY-COMPUTED.

SB Abridged Index Medicus Journals (A). Priority Journals (M).

YR 1991.

IS 0003-4975. 683.

CP UNITED-STATES (Z1.107.567.875).

IM 9105.
ND ENTRY DATE: 910228.

6

R021 Links Available
AN 91023531. 91011.
AU Losasso-T-J. Muzzi-D-A. Cucchiara-R-F.
TI Doppler detection of intravenous mannitol crystals mimics venous *air*
embolism 'letter:..
SO Anesth-Analg. 1990 Nov. 71(5). P 568-9.
JT ANESTHESIA AND ANALGESIA.
PT LETTER (LET).
LG English (EN).
MJ *EMBOLISM-AIR:* *ultrasonography* (us). MANNITOL: blood (bl). VEINS.
MN AGED. CASE-REPORT. CRANIOTOMY. CRYSTALLIZATION. HUMAN.
INTRAOPERATIVE-COMPLICATIONS. MALE.
RN 87-78-5 -- Mannitol.
SB Abridged Index Medicus Journals (A). Priority Journals (M).
YR 1990.
IS 0003-2999. 4R8.
CP UNITED-STATES (Z1.107.567.875).
IM 9101.
ND ENTRY DATE: 901119.

7

AN 90247232. 90000.
AU Kriegshauser-J-S. Reading-C-C. King-B-F. Welch-T-J.
IN Department of Diagnostic Radiology, Mayo Clinic, Rochester, MN 55905.
TI Combined systemic and portal venous gas: sonographic and CT detection
in two cases.
SO AJR-Am-J-Roentgenol. 1990 Jun. 154(6). P 1219-21.
JT AJR. AMERICAN JOURNAL OF ROENTGENOLOGY.
LG English (EN).
MJ *EMBOLISM-AIR:* diagnosis (di). PORTAL-VEIN.
TOMOGRAPHY-X-RAY-COMPUTED. *ULTRASONOGRAPHY.*
MN ABDOMINAL-NEOPLASMS: complications (co). AGED. CASE-REPORT.
EMBOLISM-AIR: etiology (et). HEPATIC-VEINS. HUMAN. INTESTINES:
blood-supply (bs). ISCHEMIA: complications (co). MALE. MESENTERY:
surgery (su). MIDDLE-AGE.
SB Abridged Index Medicus Journals (A). Priority Journals (M). Cancer
Journals (X).
YR 1990.
IS 3AE.
CP UNITED-STATES (Z1.107.567.875).
IM 9008.
ND ENTRY DATE: 900613.
CLASS UPDATE: 90.

8

AN 90182806. 90000.
AU Fong-J. Gadalla-F. Gimbel-A-A.
IN Department of Anesthesiology, New York Hospital, NY 10021.
TI Precordial Doppler diagnosis of haemodynamically compromising *air*
embolism during caesarean section.
SO Can-J-Anaesth. 1990 Mar. 37(2). P 262-4.
JT CANADIAN JOURNAL OF ANAESTHESIA.
LG English (EN).
AB This is a report of a 39-year-old parturient who had a
haemodynamically compromising venous *air* *embolism* during a repeat
Caesarean section under lumbar epidural anaesthesia. The *embolism*

occurred immediately after surgical incision during surgery in the superficial subcutaneous tissues. The diagnosis was made using intraoperative precordial ultrasonic Doppler monitoring which allowed early and successful treatment. Author-abstract.

MJ CESAREAN-SECTION: adverse-effects (ae). *EMBOLISM-AIR:* etiology (et).
INTRAOPERATIVE-COMPLICATIONS: diagnosis (di). *ULTRASONOGRAPHY.*
MN ADULT. CASE-REPORT. *EMBOLISM-AIR:* diagnosis (di). FEMALE. HUMAN.
LABOR-COMPLICATIONS. MONITORING-PHYSIOLOGIC. PRE(GNANCY).
SB Priority Journals (M).
YR 1990.
IS 0832-610X. C8L.
CP CANADA (Z1.107.567.176).
IM 9006.
ND ENTRY DATE: 900420.
CLASS UPDATE: 90.

9

AN 90176840. 90000.
AU Spencer-M-P. Thomas-G-I. Nicholls-S-C. Sauvage-L-R.
IN Providence Medical Center, Seattle, Washington.
TI Detection of middle cerebral artery emboli during carotid
endarterectomy using transcranial Doppler *ultrasonography.*
SO Stroke. 1990 Mar. 21(3). P 415-23.
JT STROKE.
LG English (EN).

AB The purpose of our study was to define the signal characteristics and clinical circumstances associated with emboli detected in the middle cerebral artery using 2-MHz pulsed transcranial Doppler ultrasound in patients undergoing carotid endarterectomy. Signals designating emboli were transients displaying harmonic qualities the signatures of which were clearly different from those of mechanical and electronic artifacts. We reviewed the audio/video tape recordings from 91 patients for signals of *air* bubble emboli occurring upon release of common carotid artery crossclamps; recordings from 35 patients (38%) demonstrated *air* bubble emboli. Transients with signatures identical to those of *air* bubble emboli were also discovered when bubbles in the bloodstream were improbable; we defined these transients as representing formed-element emboli. Such signals were found in recordings from 24 patients (26%), and they occurred before (both spontaneously and upon common carotid artery compression), during, and after surgical dissection. Signals indicating formed-element emboli were associated with intraluminal platelet thrombus, with ulcerations in the carotid artery, and with transient ischemic attacks or stroke. Most postoperative formed-element emboli did not cause symptoms but, when persisting for hours, they were associated with strokes and cerebral infarction. This Doppler ultrasound method of detecting emboli will be useful in the study of stroke mechanisms and as a clinical test to guide the medical and surgical treatment of patients at risk of stroke. Author-abstract.

MJ CAROTID-ARTERIES: surgery (su). *CEREBRAL-EMBOLISM-AND-THROMBOSIS:*
diagnosis (di). *EMBOLISM-AIR:* diagnosis (di). ENDARTERECTOMY.
ULTRASONOGRAPHY.
MN ARTERIAL-OCCLUSIVE-DISEASES: surgery (su). BLINDNESS: etiology (et).
CAROTID-ARTERY-DISEASES: surgery (su).
CEREBRAL-EMBOLISM-AND-THROMBOSIS: etiology (et). *EMBOLISM-AIR:*
etiology (et). ENDARTERECTOMY: adverse-effects (ae). HUMAN.
INTRAOPERATIVE-COMPLICATIONS. SKULL. SUPPORT-NON-U-S-GOVT.
ULTRASONOGRAPHY: methods (mt).
SB Priority Journals (M).

YR 1990.
IS 0039-2499. V2J.
CP UNITED-STATES (Z1.107.567.875).
IM 9006.
ND ENTRY DATE: 900411.
CLASS UPDATE: 90.

10

AN 90166772. 90000.
AU Deverall-P-B. Padayachee-T-S. Parsons-S. Theobald-R.
Battistessa-S-A.
IN Department of Cardiothoracic Surgery, Guy's Hospital, London, UK.
TI Ultrasound detection of micro-emboli in the middle cerebral artery
during cardiopulmonary bypass surgery.
SO Eur-J-Cardiothorac-Surg. 1988. 2(4). P 256-60.
JT EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY.
LG English (EN).
AB The occurrence of neurological sequelae following cardiopulmonary
bypass (CPB) surgery has stimulated interest in refining the
techniques of extracorporeal circulation. *Air* micro-emboli
originating from the oxygenator have been postulated as one source of
cerebral damage. Since controversy still exists regarding the merits
of bubble versus membrane oxygenators, this has prompted
investigators to devise methods to determine the amount of
micro-emboli produced during CPB. In this study, 27 patients
undergoing CPB surgery for coronary artery disease (21) or valve
replacement (6) were examined. The surgical and anaesthetic
techniques were standardised in all patients except for the type of
oxygenator used. A bubble oxygenator was used in 17 patients
(Bentley Bio-10, William Harvey or Dideco) and a membrane oxygenator
with a 25 microns filter in the remaining 10 patients (Bentley BOS
CM50). Transcranial pulsed Doppler ultrasound was used to obtain
blood velocity signals from the middle cerebral artery throughout
CPB. A flow disturbance index (FDI) was defined which provided a
representative index of the number of micro-emboli passing the
ultrasound transducer. The FDI indicated the presence of gaseous
micro-emboli during insertion of the aortic cannula in 22 of the 27
patients. In the 17 patients with a bubble oxygenator, the FDI
ranged from 4-39. In the 10 patients with a membrane oxygenator, the
FDI was always 0. Variation of gas flow rates in 3 patients with
bubble oxygenators showed a change in the FDI from 4 +/- 4 at a flow
rate of 2 l/min to 17 +/- 9 at 5 l/min. (ABSTRACT TRUNCATED AT 250
WORDS). Author-abstract.
MJ CARDIOPULMONARY-BYPASS: adverse-effects (ae).
CEREBRAL-EMBOLISM-AND-THROMBOSIS: diagnosis (di). *EMBOLISM-AIR:*
diagnosis (di). OXYGENATORS: adverse-effects (ae). *ULTRASONOGRAPHY.*
MN ADULT. CEREBRAL-ARTERIES: physiopathology (pp).
CEREBRAL-EMBOLISM-AND-THROMBOSIS: etiology (et). *EMBOLISM-AIR:*
etiology (et). HUMAN. INTRAOPERATIVE-PERIOD. MIDDLE-AGE. OXYGEN:
blood (bl). REGIONAL-BLOOD-FLOW.
RN 7782-44-7 -- Oxygen.
SB Priority Journals (M).
YR 1988.
IS 1010-7940. AOJ.
CP GERMANY-WEST (Z1.542.315.570).
IM 9006.
ND ENTRY DATE: 900411.
CLASS UPDATE: 90.

AN 90120067. 90000.
 AU Muzzi-D-A. Losasso-T-J. Black-S. Nishimura-R.
 IN Department of Anesthesiology, Mayo Medical School, Rochester,
 Minnesota.
 TI Comparison of a transesophageal and precordial ultrasonic Doppler
 sensor in the detection of venous *air* *embolism*.
 SO Anesth-Analg. 1990 Jan. 70(1). P 103-4.
 JT ANESTHESIA AND ANALGESIA.
 LG English (EN).
 MJ *EMBOLISM-AIR:* diagnosis (di). *ULTRASONOGRAPHY*.
 MN COMPARATIVE-STUDY. ECHOCARDIOGRAPHY-DOPPLER. ESOPHAGUS. HUMAN.
 SB Abridged Index Medicus Journals (A). Priority Journals (M).
 YR 1990.
 IS 0003-2999. 4R8.
 CP UNITED-STATES (Z1.107.567.875).
 IM 9004.
 ND ENTRY DATE: 900221.
 CLASS UPDATE: 90.

12

AN 89287930. 89000.
 AU McFadden-S. Dunlop-W-E.
 IN Department of Surgery, Calgary General Hospital, Alta.
 TI Hepatic portal venous gas in adults: importance of *ultrasonography* in
 early diagnosis and survival.
 SO Can-J-Surg. 1989 Jul. 32(4). P 297-8.
 JT CANADIAN JOURNAL OF SURGERY.
 LG English (EN).
 AB Hepatic portal venous gas (HPVG) is an ominous radiologic sign and
 indicates the need for urgent surgical intervention. The causes are
 varied, but the commonest and most serious is infarcted bowel.
 Because HPVG is difficult to detect on plain abdominal x-ray films,
 more reliable methods have been sought. The authors describe the
 case of a 31-year-old man to illustrate the need for and benefit of
 early detection of HPVG using *ultrasonography,* which was instrumental
 in the survival of the patient. Author-abstract.
 MJ *EMBOLISM-AIR:* diagnosis (di). PORTAL-VEIN. *ULTRASONOGRAPHY*.
 MN ADULT. CASE-REPORT. EVALUATION-STUDIES. HUMAN. MALE.
 TIME-FACTORS.
 SB Priority Journals (M).
 YR 1989.
 IS 0008-428X. CKJ.
 CP CANADA (Z1.107.567.176).
 IM 8910.
 ND ENTRY DATE: 890810.
 CLASS UPDATE: 90.

13

AN 88239801. 88000.
 AU Padayachee-T-S. Parsons-S. Theobald-R. Gosling-R-G. Deverall-P-B.
 IN Department of Radiological Sciences, Guy's Hospital, London, England.
 TI The effect of arterial filtration on reduction of gaseous microemboli
 in the middle cerebral artery during cardiopulmonary bypass.
 SO Ann-Thorac-Surg. 1988 Jun. 45(6). P 647-9.
 JT ANNALS OF THORACIC SURGERY.
 LG English (EN).
 AB Noninvasive in vivo detection of gaseous microemboli in the middle
 cerebral artery, by transcranial Doppler ultrasound, was used to
 determine the effect of filtration in the arterial catheter using 25-
 and 40-microns filters and bubble oxygenators in patients undergoing

cardiopulmonary bypass surgery. Eighteen patients undergoing coronary artery bypass surgery were studied using a closed cardiac (unvented heart) model. Group 1 patients (no filters) had the highest incidence of gaseous microemboli, as indicated by the ultrasound microemboli index, at both high and low oxygen flow rates. Group 2 patients (40-microns filters) had a significantly lower microemboli index, particularly at low oxygen flow rates ($t = 4.9$, p less than 0.001). The 25-microns group patients had the lowest values of all. No microemboli were detected at low oxygen flow rates, and microemboli were detected in only 0.1% of the samples at high oxygen flow rates. Additionally, observations on vented hearts in 3 patients undergoing cardiac valve surgery indicate that the origin of gaseous microemboli may be *air* trapped inside the heart. Author-abstract.

MJ CARDIOPULMONARY-BYPASS. *CEREBRAL-EMBOLISM-AND-THROMBOSIS:* prevention-and-control (pc). *EMBOLISM-AIR:* prevention-and-control (pc). FILTRATION: instrumentation (is). OXYGENATORS. *ULTRASONOGRAPHY.*
MN CEREBRAL-ARTERIES: pathology (pa). *CEREBRAL-EMBOLISM-AND-THROMBOSIS:* diagnosis (di). COMPARATIVE-STUDY. *EMBOLISM-AIR:* diagnosis (di). HUMAN. INTRAOPERATIVE-CARE: methods (mt). INTRAOPERATIVE-COMPLICATIONS: prevention-and-control (pc). MIDDLE-AGE. SUPPORT-NON-U-S-GOVT.
SB Abridged Index Medicus Journals (A). Priority Journals (M).
YR 1988.
IS 0003-4975. 683.
CP UNITED-STATES (Z1.107.567.875).
IM 8809.
ND ENTRY DATE: 880706.
CLASS UPDATE: 90.

14

AN 88220825. 88000.
AU Gibby-G-L.
TI Precordial Doppler is not obsolete for venous *air* *embolism* monitoring 'letter:.
SO Anesthesiology. 1988 May. 68(5). P 829.
JT ANESTHESIOLOGY.
LG English (EN).
MJ *EMBOLISM-AIR:* diagnosis (di). MONITORING-PHYSIOLOGIC: instrumentation (is). *ULTRASONOGRAPHY:* instrumentation (is). VEINS:
MN HUMAN.
SB Abridged Index Medicus Journals (A). Priority Journals (M).
YR 1988.
IS 0003-3022. 4SG.
CP UNITED-STATES (Z1.107.567.875).
IM 8808.
ND ENTRY DATE: 880614.
CLASS UPDATE: 90.

15

AN 88211607. 88000.
AU Robberecht-E-A. Afschrift-M. De-Bel-C-E. Van-Haesebrouck-P-J. Van-Bever-H-P. De-Wit-M. Leroy-J-G.
IN Children's Hospital C. Hooft, Ghent, Belgium.
TI Sonographic demonstration of portal venous gas in necrotizing enterocolitis.
SO Eur-J-Pediatr. 1988 Feb. 147(2). P 192-4.
JT EUROPEAN JOURNAL OF PEDIATRICS.
LG English (EN).

AB Portal vein gas *embolism* was demonstrated by ultrasound in a preterm infant with necrotizing enterocolitis. This sign could not be detected radiographically. It is speculated that portal venous gas occurs more frequently than hitherto inferred from radiological studies. This observation points to the value of *ultrasonography* in providing early objective evidence in support of the diagnosis of NEC. The favourable outcome for the patient proves that portal venous gas *embolism* is not necessarily associated with a fulminant course of enterocolitis. Author-abstract.

MJ *EMBOLISM-AIR:* diagnosis (di). ENTEROCOLITIS-PSEUDOMEMBRANOUS: diagnosis (di). PORTAL-VEIN: pathology (pa). *ULTRASONOGRAPHY.*

MN CASE-REPORT. *EMBOLISM-AIR:* etiology (et). ENTEROCOLITIS-PSEUDOMEMBRANOUS: complications (co). HUMAN. INFANT-NEWBORN. MALE.

SB Priority Journals (M).

YR 1988.

IS 0340-6199. END.

CP GERMANY-WEST (Z1.542.315.570).

IM 8808.

ND ENTRY DATE: 880614.

CLASS UPDATE: 90.

16

AN 88117638. 88000.

AU Gibby-G-L. Ghani-G-A.

IN Department of Anesthesiology, University of Florida College of Medicine, Gainesville.

TI Computer-assisted Doppler monitoring to enhance detection of *air* emboli.

SO J-Clin-Monit. 1988 Jan. 4(1). P 64-73.

JT JOURNAL OF CLINICAL MONITORING.

LG English (EN).

AB Currently, two of the most sensitive clinical approaches commonly used to monitor for venous *air* *embolism,* i.e., precordial Doppler audio and capnography, require the attention of the anesthesiologist's eye or ear, which is a distraction from other aspects of care. To assess the feasibility of allowing the computer to relieve the necessity for continuous human monitoring, we developed a computer algorithm for monitoring the precordial Doppler audio. This algorithm extracted (1) the amplitude of certain higher-frequency components of the Doppler audio, (2) a measure of the average value of the envelope of Doppler audio, and (3) the ratio between the average value of the Doppler envelope and the amount of envelope signal variation at heart rate frequency and its multiples. These three features were monitored by an adaptive pattern recognition algorithm that compared each new value for each feature with the previously developed mean and standard deviation for that feature. If the changes in the three features exceeded a detection threshold, an alarm (indicating suspected *air* *embolism*) was activated. Implemented as a prototype system, the algorithm was given preliminary testing in 2 dogs and activated alarms at levels of *air* well below those reported to cause clinically significant hemodynamic changes in dogs. While decreasing the distraction for the anesthesiologist, this early prototype alarm system alerts its user to the need for analysis of the Doppler signals when it senses an *air* embolus. Author-abstract.

MJ ALGORITHMS. *EMBOLISM-AIR:* diagnosis (di). MONITORING-PHYSIOLOGIC: methods (mt). SIGNAL-PROCESSING-COMPUTER-ASSISTED. *ULTRASONOGRAPHY:* methods (mt).

MN FLOWMETERS. FOURIER-ANALYSIS. HUMAN.

SB Priority Journals (M).
YR 1988.
IS 0748-1977. JCM.
CP UNITED-STATES (Z1.107.567.875).
IM 8805.
ND ENTRY DATE: 880315.
CLASS UPDATE: 90.

17

AN 87239469. 87000.
AU Malinow-A-M. Naulty-J-S. Hunt-C-O. Datta-S. Ostheimer-G-W.
IN Department of Anaesthesia, Brigham and Women's Hospital, Harvard
Medical School, Boston, Massachusetts.
TI Precordial ultrasonic monitoring during cesarean delivery.
SO Anesthesiology. 1987 Jun. 66(6). P 816-9.
JT ANESTHESIOLOGY.
LG English (EN).
MJ CESAREAN-SECTION: adverse-effects (ae). CHEST-PAIN: etiology (et).
DYSPNEA: etiology (et). *EMBOLISM-AIR:* diagnosis (di).
ULTRASONOGRAPHY.
MN *EMBOLISM-AIR:* etiology (et). FEMALE. HUMAN. PREGNANCY.
ULTRASONICS.
SB Abridged Index Medicus Journals (A). Priority Journals (M).
YR 1987.
IS 0003-3022. 4SG.
CP UNITED-STATES (Z1.107.567.875).
IM 8709.
ND ENTRY DATE: 870629.
CLASS UPDATE: 90.

18

AN 87038316. 87000.
AU Grant-J. Murphy-J-F.
TI Pulsed Doppler diagnosis of cerebral *air* embolus in a baby with
pulmonary interstitial emphysema 'letter:'.
SO Lancet. 1986 Oct 25. 2(8513). P 983-4.
JT LANCET.
LG English (EN).
MJ *CEREBRAL-EMBOLISM-AND-THROMBOSIS:* diagnosis (di). *EMBOLISM-AIR:*
diagnosis (di). INFANT-PREMATURE-DISEASES: diagnosis (di).
PULMONARY-EMPHYSEMA: complications (co). *ULTRASONOGRAPHY.*
MN CASE-REPORT. HUMAN. INFANT-NEWBORN.
SB Abridged Index Medicus Journals (A). Priority Journals (M). Cancer
Journals (X).
YR 1986.
IS 0023-7507. LOS.
CP ENGLAND (Z1.542.363.300).
IM 8702.
ND ENTRY DATE: 861124.
CLASS UPDATE: 90.

19

AN 86321131. 86000.
AU Azad-S-S. Maguire-D. Goldberg-M-E.
IN Department of Anesthesiology, Jefferson Medical College of Thomas
Jefferson University, Philadelphia, Pennsylvania.
TI Junctional rhythm can mimic *air* *embolism* during precordial Doppler
monitoring 'published erratum appears in Anesth Analog 1987
Jan;66(1):100:'.
SO Anesth-Analg. 1986 Oct. 65(10). P 1083-4.

JT ANESTHESIA AND ANALGESIA.

LG English (EN).

MJ *EMBOLISM-AIR:* diagnosis (di). HEART-RATE. *ULTRASONOGRAPHY.*

MN AGED. CASE-REPORT. DIAGNOSIS-DIFFERENTIAL. HUMAN. MALE.

SB Abridged Index Medicus Journals (A). Priority Journals (M).

YR 1986.

IS 0003-2999. 4R8.

CP UNITED-STATES (Z1.107.567.875).

IM 8612.

ND ENTRY DATE: 861021.

LAST REVISION DATE: 870210.

CLASS UPDATE: 90.

20

AN 86132259. 86000.

AU Fataar-S. Cadogan-E. Spruyt-O.

IN Department of Radiology, Green Lane Hospital, Auckland, New Zealand.

TI *Ultrasonography* of hepatic portal venous gas due to diverticulitis.

SO Br-J-Radiol. 1986 Feb. 59(698). P 183-5.

JT BRITISH JOURNAL OF RADIOLOGY.

LG English (EN).

MJ DIVERTICULITIS-COLONIC: complications (co). *EMBOLISM-AIR:* diagnosis (di). PORTAL-VEIN. *ULTRASONOGRAPHY.*

MN CASE-REPORT. *EMBOLISM-AIR:* etiology (et). HUMAN. LIVER: blood-supply (bs). MALE. MIDDLE-AGE.

SB Abridged Index Medicus Journals (A). Priority Journals (M). Cancer Journals (X).

YR 1986.

IS 0007-1285. B28.

CP ENGLAND (Z1.542.363.300).

IM 8606.

ND ENTRY DATE: 860404.

CLASS UPDATE: 90.

21

AN 86129036. 86000.

AU Porcel-A. Taboury-J. Aboulker-C. Berrod-J-L. Tubiana-J-M.

TI *Air* in the portal system and mesenteric infarction. Value of ultrasonic examination. Apropos of a case:.

TT Aeroportie et infarctus mesenterique. Interet de l'examen echographique. A propos d'une observation.

SO Ann-Radiol (Paris). 1985. 28(8). P 615-7.

JT ANNALES DE RADIOLOGIE.

LG French (FR).

MJ *EMBOLISM-AIR:* etiology (et). INFARCTION: complications (co). INTESTINE-SMALL: blood-supply (bs). PORTAL-SYSTEM: pathology (pa). *ULTRASONOGRAPHY.*

MN ADULT. CASE-REPORT. *EMBOLISM-AIR:* diagnosis (di). ENGLISH-ABSTRACT. HUMAN. MALE.

YR 1985.

IS 0003-4185. 5W6.

CP FRANCE (Z1.542.286).

IM 8605.

ND ENTRY DATE: 860318.

CLASS UPDATE: 90.

END OF DOCUMENTS IN LIST

APPENDIX E

List of Ultrasound Manufacturing/R&D Organizations

Ultrasound Equipment Manufacturers

Company Name: **Acoustic Imaging Technologies**
Address: 10027 S. 51st St.
Phoenix, AZ 85004

Area(s) of expertise: Duplex scanners

Contact Person: Kerr Spencer
Phone: 602-496-6681 (602-820-3187 old #?)
FAX: 602-496-6679

Notes: Owned by Dornier Medical Systems

Company Name: **Acuson, Inc.**
Address: 1220 Charleston St.
P.O. Box 7393
Mountain View, CA 94039

Area(s) of expertise: Duplex scanners

employees: 1,000
yrs in business: 11
\$ annual sales: \$227M

Contact Person: Ron Bucheger, VP Mktg.
Phone: 415-969-9112
FAX: 415-964-8331

Company Name: **Advanced Medical Devices, Inc.**
Address: 2733 Saunders Street
Camden, NJ 08105

Area(s) of expertise: Transducers

employees: 20
yrs in business: 5
\$ annual sales: \$1 M

Contact Person: Mark Orvak, Pres.
Phone: 609-964-8448
FAX: 609-365-8065

Company Name: **Advanced Medical Systems**
Address: 925 Sherman Ave.
Hamden, CT 06514

of employees: 45
yrs in business:
\$ annual sales: \$4.5 M

Contact Person:
Phone: 800-325-2070 203-245-0500
FAX: 203-288-9032

Company Name: **Advanced Technology Laboratories**
Address: 22100 Bothell Hwy. SE
P.O. Box 3003
Bothell, WA 98041

Area(s) of expertise: Duplex scanners

employees: 1,500
yrs in business: 10 +
\$ annual sales: \$365 M

Contact Person: Chuck Boyle, VP/product development
Phone: 1-800-982-2011 206-487-7000
FAX: 206-485-3680

Notes: Owned by Westmark International

Company Name: **Applied Biometrics, Inc.**
Address: 6269 Bury Drive
Eden Prairie, MN 55346

Area(s) of expertise: Cardiac output with pulse doppler transducer at tip of transtracheal tube

employees: 17
yrs in business: 7
\$ annual sales: still in development of C.O. monitor

Contact Person: Chris Peterson, Engineering Manager
Phone: 612-934-8849
FAX: 612-934-8837

Company Name: **Biomedicus, Inc.**
Address: 9600 w. 76th St.
Eden Prairie, MN 55345

employees: 160
yrs in business:
\$ annual sales: \$41 M

Contact Person: James Lyons, Pres.
Phone: 800-328-4434 612-944-7784
FAX: 612-944-7557

Company Name: **Biosound, Inc.**
Address: 7990 Castleway Drive
Indianapolis, IN 46250

employees: 200
yrs in business: 11
\$ annual sales: \$50 M

Contact Person: Barbara Wolf, Mgr./Ultrasound
Phone: 800-428-4374 317-849-1793
FAX: 317-841-8616

Notes: Owned by Esaote Biomedica

Company Name: **Bruel & Kjaer Instruments, Inc.**
Address: 185 Forest St.
Marlborough, MA 01752

employees: 215
yrs in business: 15
\$ annual sales: \$20 M

Contact Person: Ralph Winter, U.S. Mktg. Mgr.
Phone: 800-876-7226 508-481-7000
FAX: 508-485-0519

Notes: All R&D/manufacturing done in Denmark

Company Name: **Carolina Medical Electronics, Inc.**
Address: 157 Industrial Drive
P.O. Box 307
King, NC 27021

Area(s) of expertise: Electromagnetic flowmetry

employees: 45
yrs in business: 30
\$ annual sales: \$3 M

Contact Person: Richard Hager, Dir. Engr.
Phone: 800-334-4531 919-983-5132
FAX: 919-983-8992

Company Name: **Circadian, Inc.**
Address: 3942 N. 1st St.
San Jose, CA 95134

employees: 180
yrs in business:
\$ annual sales: \$2 M

Contact Person: Ron Lou
Phone: 800-669-7001 408-943-9222
FAX: 408-434-9585

Company Name: **Corometrics Medical Systems, Inc.**
Address: 61 Barnes Park Rd. N.
P.O. Box 333
Wallingford, CT 06492

Area(s) of expertise: Fetal ultrasound monitoring

employees: 700
yrs in business:
\$ annual sales:

Contact Person: Dan Boucher, VP
Phone: 800-243-3952 203-265-5631
FAX: 203-284-9465

Notes: Owned by American Home Products Corp.

Company Name: **Crystal Biotech, Inc.**
Address: 75 South St.
Hopkinton, MA 01748

employees: 6
yrs in business: 4
\$ annual sales:

Contact Person: Jane Hasson
Phone: 800-325-5977 508-435-9039
FAX: 508-435-2165

Notes: Invasive ultrasound - mostly for animal research

Company Name: **Diagnostic Ultrasound Corp.**
Address: P.O. Box 789
Kirkland, WA 98083

Area(s) of expertise: Urology/ Portable bladder volume/flow

employees: 20
yrs in business: 7
\$ annual sales:

Contact Person: Gerald McMorrow, Pres.
Phone: 800-331-2313 206-828-3860
FAX: 206-827-8324

Company Name: **Diasonics, Inc.**
Address: 1565 Barber Lane
Milpitas, CA 95035

Area(s) of expertise: Duplex scanner

employees: 1,600
yrs in business: 13
\$ annual sales: \$280 M

Contact Person: Chris Bohl
Phone: 800-421-1968
FAX:

Notes: Owned by Toshiba Corp.

Company Name: **Dymax Corp.**
Address: 604 Epsilon Drive
Pittsburgh, PA 15238

Area(s) of expertise: Ultrasound probes, annular probes (3D imaging)

employees: 26
yrs in business: 10
\$ annual sales: \$2 M

Contact Person: Phil Mattheis
Phone: 412-963-6884
FAX: 412-963-6179

Notes: Manufacturing, R&D in Norway

Company Name: **Eden Medical Electronics, Inc.**
Address: 19226 66th Ave. South
Suite L103
Kent, WA 98032

Area(s) of expertise: Transcranial doppler, air-embolism detector

employees: > 25 —
yrs in business: 8 —
\$ annual sales: \$2 M —

Contact Person: John McCartney, VP/Engr. —
Phone: 800-323-3336 206-656-8330 —
FAX: 408-980-9662 —

Notes: Owned by Eden Medical Electronics GMBH, TCD/NASA/shuttle —
experience (Prof. Alec Eden - W. Germany) —

Company Name: **Electro-Diagnostic Instruments** —
Address: 3401 Winona Ave. —
Burbank, CA 91504 —

employees: 18 —
yrs in business: 20 —
\$ annual sales: \$2 M —

Contact Person: Bob Smith, Pres. —
Phone: 800-334-9944 213-849-7701 —
FAX: 818-843-0905 —

Company Name: **Elscent, Inc.** —
Address: P.O. Box 679 —
Boston, MA 02215 —

Area(s) of expertise: Ultrasonic (general purpose) scanner —

employees: 2,400 —
yrs in business: 8 —
\$ annual sales: \$156 M —

Contact Person: Doron Hess, Dir. Engr./Ultrasound —
Phone: 201-342-2020 —
FAX: 201-342-3782 —

Notes: Owned by Elscint, Ltd., R&D/manufacturing facilities in Israel —

Company Name: **EMS Medical, Inc.** —
Address: 302 Lindbergh Ave. —
Livermore, CA 94550 —

Area(s) of expertise: Fetal ultrasound monitor —

employees: 15 —
yrs in business: 10 —
\$ annual sales: \$2.5 M —

Contact Person: Paul Ulbrich, Pres.
Phone: 415-449-3382
FAX: 510-449-0887

Company Name: **GE Medical Systems**
Address: Box 414
Milwaukee, WI 53201

Area(s) of expertise: Duplex scanners

employees: 9,200

yrs in business:

\$ annual sales:

Contact Person: Michael Ahlund
Phone: 414-647-4404
FAX: 414-544-3358

Notes: Multi-modality medical imaging company

Company Name: **Hewlett-Packard**
Address: 3000 Minuteman Rd.
Andover, MA 01810

Area(s) of expertise: Duplex scanners

employees:

yrs in business:

\$ annual sales:

Contact Person: Mark Ringle
Phone: 508-687-1501
FAX: 508-689-9862

Notes: Formerly Ekoline ultrasound

Company Name: **Hoffrel Instruments, Inc.**
Address: 345-A Wilson Ave.
P.O. Box 5825
South Norwalk, CT 06854

Area(s) of expertise: Custom transducers

employees: 12

yrs in business: 28

\$ annual sales: \$1 M

Contact Person: Russel Uphoff, Pres.

Phone: 203-866-9205
FAX: 203-866-9207

Notes: Trasesophageal doppler for bubble detection (in heart) during neurosurgery

Company Name: **Craig Hartley, PhD**
Address: Baylor College of Medicine
Houston, TX

Area(s) of expertise: Currently building ultrasound imagers (20MHz) for small animals

Contact Person: Craig Hartley, PhD
Phone: 713-798-4195
FAX: 713-796-0015

Notes: Custom Research/Engineering lab

Company Name: **Hokanson, Inc., D.E.**
Address: 12840 NE 21st Pl.
Bellevue, WA 98005

Area(s) of expertise: Duplex scanners

employees: 18
yrs in business:
\$ annual sales: \$1.3 M

Contact Person: Gene Hokanson, Pres.
Phone: 800-999-8251 206-882-1689
FAX: 206-881-1636

Company Name: **Horizons Research Labs, Inc.**
Address: 2155 North State Road 7
Margate, FL 33063

Contact Person:
Phone: 800-327-1074 305-735-8500
FAX: 305-974-2302

Company Name: **Huntleigh Technology**
Address: 227 Route 33 East
Manalapan, NJ 07726

Area(s) of expertise: Hand-held "pocket" dopplers, Fetal ultrasound monitor

employees: 400 (worldwide)
yrs in business: 12 in ultrasonic, 23 in medical electronics
\$ annual sales:

Contact Person: Andy Wood - Ultrasound Product Mgr.
Phone: 800-223-1218 908-446-2500
FAX: 908-446-1938

Notes: U.S. Subsidiary of Huntleigh Technology, UK., All R&D/Manuf. in UK.

Company Name: **Imex Medical Systems, Inc.**
Address: 6355 Joyce Dr.
Golden, CO 80403

employees: 75
yrs in business:
\$ annual sales: \$6 M

Contact Person: Tom Doggett
Phone: 800-525-2519 303-431-9400
FAX: 303-431-0429

Company Name: **Institute of Applied Physiology and Medicine**
Address: 701 16th Avenue
Seattle, WA 98122

Area(s) of expertise: Air-embolism detector

employees: 4
yrs in business: 20
\$ annual sales: \$1 M

Contact Person: John Klepper, PhD
Phone: 206-553-7330
FAX: 206-553-1717

Company Name: **International Ultrasound Systems**
Address: 12 Overlook Park
Rochelle Park, NJ

Contact Person: Raul Gutierrez, V.P.
Phone: 800-736-1826 201-843-1807
FAX: 201-843-2035

Company Name: **Interspec**

Address: 110 W. Butler Ave.
Ambler, PA 19002

Area(s) of expertise: Duplex scanners

employees: 205
yrs in business: 10
\$ annual sales: \$57 M

Contact Person: Art Schenck, V.P.
Phone: 800-332-3246 215-540-9190
FAX: 215-540-9711

Company Name: **Interventional Technologies, Inc.**
Address: 3574 Ruffin Rd.
San Diego, CA 92132

Area(s) of expertise: Contract R&D

employees: 10
yrs in business:
\$ annual sales:

Contact Person: Herb Radish
Phone: 619-541-2840
FAX: 619-292-8381

Company Name: **Kesa Corp.**
Address: 4701 Patrick Henry Dr., Suite 1801
Santa Clara, CA 95054

Area(s) of expertise: Development company/contract research

employees: 9
yrs in business: 10
\$ annual sales:

Contact Person: Steve Ghlback, PhD, Pres.
Phone: 408-748-1814
FAX: 408-748-0664

Company Name: **KB-Aerotech**
Address: Box 350
Lewistown, PA 17044

Area(s) of expertise: Ultrasound Transducers

employees: 250
yrs in business:
\$ annual sales: \$18 M

Contact Person:
Phone: 800-233-7183 717-242-0327
FAX: 717-242-2606

Notes: Owned by Emerson Electric Co.

Company Name: **Kontron Instruments, Inc.**
Address: 9 Plymouth St.
Everett, MA 02149

employees: 280
yrs in business:
\$ annual sales: \$2 M

Contact Person:
Phone: 800-343-3297 617-389-6400
FAX: 617-387-2157

Notes: Owned by Kontron Holding NV

Company Name: **Konigsberg Instruments, Inc.**
Address: 2000 Foothill Blvd.
Pasadena, CA 91107

Area(s) of expertise: Hybrid microcircuits, pressure transducers, custom subassy's

employees: 30
yrs in business:
\$ annual sales: \$1.3 M

Contact Person: Bill Mills, Chief Engineer
Phone: 818-449-0016
FAX: 818-449-1086

Company Name: **Koven and Associates**
Address: 13044 Ferncrest Ct.
St. Louis, MO 63141

Area(s) of expertise: Doppler vascular flowmeters

employees:
yrs in business:
\$ annual sales:

Contact Person: Paul Koven
Phone: 314-731-0008
FAX: 314-731-2946

Notes: U.S. representatives for Hayashi Denki Co. (HADECO - Japan)

Company Name: **Life-Tech, Inc.**
Address: P.O. Box 36221
Houston, TX 77236

employees: 86
yrs in business:
\$ annual sales: \$7 M

Contact Person:
Phone: 800-231-9841 713-495-9411
FAX: 713-495-7960

Company Name: **Life Sciences, Inc.**
Address: West Lebanon, NH

Contact Person: Allan Heath
Phone: 1-800-343-0693
FAX: 603-298-5942

Company Name: **Medasonics, Inc.**
Address: 47233 Fremont Blvd.
Fremont, CA 94539

Area(s) of expertise: Pulsed and CW Duplex scanners

employees: 100
yrs in business: 21
\$ annual sales:

Contact Person: Jerry Smith
Phone: 800-227-8076 415-623-0626
FAX: 415-623-0708

Notes: Owned by Settsu P.B. Manufacturing (Japan).

Company Name: **Medical Accessories, Inc.**
Address: 92 Youngs Road
Trenton, NJ 08619

Area(s) of expertise: Transducers, EKG electrodes, Fetal monitors

employees: 15
yrs in business: 24
\$ annual sales:

Contact Person: Janis Ziedonis
Phone: 609-890-8304
FAX: 609-890-0638

Notes: Previous NASA collaborations. Competed w/ Techno-Scientific for design of previous ultrasound air-embolism detector for NASA.

Company Name: **Millar Instruments, Inc.**
Address: P.O. Box 230227
Houston, TX 77223

Area(s) of expertise: Miniature pressure xdcrs, catheter ultrasound probes

employees: 48
yrs in business: 15
\$ annual sales: \$4 M

Contact Person: Huntley Millar, Pres.
Phone: 800-669-2343 713-923-9171
FAX: 713-923-7757

Company Name: **Minntech Corp.**
Address: 14905 28th Ave. North
Minneapolis, MN 55441

employees: 200
yrs in business:
\$ annual sales: \$32 M

Contact Person: Dan Schyma
Phone: 800-328-3340 612-553-3300
FAX: 612-553-3387

Company Name: **Multigon Industries**
Address: 559 Gramatan Avenue
Mt. Vernon, NY 10552

Area(s) of expertise: Transcranial doppler

employees: 10
yrs in business:
\$ annual sales:

Contact Person: Bill Stern

Phone: 800-289-6858 914-472-1697
FAX: 914-664-9502

Notes: Formerly Unigon Industries

Company Name: **Nuclear Associates**
Address: 100 Voice Road
Carle Place, NY 11514

employees: 34
yrs in business:
\$ annual sales:

Contact Person: Martin Ratner, Dir. Mktg.
Phone: 516-741-6360
FAX: 516-741-5414

Notes: Owned by Victoreen, Inc.

Company Name: **Oxford Medical, Inc.**
Address: 11526 53rd Street N.
Clearwater, FL 34620

Area(s) of expertise: Air-embolism detector, Ambulatory EEG, Holter, BP

employees: 35
yrs in business: 25
\$ annual sales: \$10 M

Contact Person: Jean Rizzotte
Phone (US): 800-237-8923 813-573-4500
FAX (US): 813-572-6836

Notes: Owned by Oxford Medical, Ltd, (UK). All R&D done in UK. Oxford acquired Sonicaid in 1987. UK R&D Mgr: John Francis (011-0235-533433)

Company Name: **Parks Medical Electronics, Inc.**
Address: P.O. Box 5669
Aloha, OR 97006

Area(s) of expertise: Air embolism detector (Model 915-AL)

employees: 60
yrs in business: 25+
\$ annual sales: \$5 M

Contact Person: Larry Smurthwaite

Phone: 800-547-6427 503-649-7007
FAX: 503-591-9753

Company Name: **Phillips Ultrasound International NA)**
Address: 2722 South Fairview St.
Santa Ana, CA 92704

Area(s) of expertise: Duplex scanners

employees: 30 (in ultrasound)
yrs in business:
\$ annual sales:

Contact Person: Allan Schultz, Mgr/Marketing
Phone: 714-241-5259
FAX: 714-241-5420

Notes: Owned by Philips Medical Systems, NA

Company Name: **PIE Medical**
Address: 3535 Route 66
Neptune, NJ 07753

Area(s) of expertise: Portable dopplers

employees: 18
yrs in business: 15
\$ annual sales: \$2.6 M

Contact Person: Mike Tunnicliffe
Phone: 800-722-6400 908-922-4888
FAX: 908-922-3561

Notes: Owned by PIE Medical (Holland). All R&D done in Holland.

Company Name: **The Probe Corp.**
Address: 11662 Lake Shore Place
North Palm Beach, FL 33408

employees: 6
yrs in business: 2
\$ annual sales: \$1.5 M

Contact Person:
Phone: 407-626-4405
FAX:

Company Name: **Quantum Medical Systems**

Address: 1040 12th Ave. NW
Issaquah, WA 98027

Area(s) of expertise: Duplex scanners, vascular imaging

employees: 160

yrs in business:

\$ annual sales:

Contact Person: Ray Powis

Phone: 800-367-3569 206-392-9180

FAX: 206-391-9161

Notes: Recently acquired by Siemens Ultrasound.

Company Name: **Sarns, Inc.**

Address: 6200 Jackson Rd.
Ann Arbor, MI 48106

Area(s) of expertise: Air detector for heart/lung bypass machine

employees: 240

yrs in business:

\$ annual sales: 20,000,000

Contact Person: Fred Gruhl, Dir. R&D

Phone: 800-262-3304 313-663-4145

FAX: 313-663-5062

Notes: Owned by 3M/Medical-Surgical Division

Company Name: **Scientronics Manufacturing**

Address: Flowerfield Bldg. 1
St. James, NY 11780

Contact Person: Kerrence Gaffington

Phone: 516-584-6640

FAX: 516-584-6806

Company Name: **Shimadzu Medical Systems**

Address: 101 W. Walnut
Gardena, CA 90248

Area(s) of expertise: Duplex scanners, OB/GYN

employees: 32

yrs in business:

\$ annual sales: \$5 M

Contact Person: Debbi Zane, Dir. R&D
Phone: 800-228-1429 213-217-8855
FAX: 213-217-0661

Company Name: **Techno Scientific, Inc.**
Address: 60 Caster Ave.
Woodbridge, Ontario L4L 5Y9

Area(s) of expertise: Air embolism detector

employees: 5
yrs in business: 6
\$ annual sales: < \$1 M

Contact Person: Victoria McDonald
Phone: 416-851-9958
FAX: 416-851-6314

Notes: Developed previous NASA doppler air embolism detector. Diving/Canadian Navy experience.

Company Name: **Tetrad Corp.**
Address: 12741 East Caley Ave., Unit 126
Englewood, CO 80111

Area(s) of expertise: Doppler module/designs for large ultrasound OEM's.

employees: 9
yrs in business: 6
\$ annual sales:

Contact Person: Said Azim, PhD
Phone: 303-790-7239
FAX: 303-790-2726

Company Name: **Toshiba America Medical Systems**
Address: 2441 Michelle Dr.
Tustin, CA 92681

Area(s) of expertise: Ultrasound scanners

employees: 1,300
yrs in business:
\$ annual sales: \$300 M

Contact Person: Tom Jedrzejewicz, Mktg.

Phone: 800-421-1968 714-730-5000
FAX: 714-832-3990

Notes: Owned by Toshiba Corp. All R&D/manufacturing done in Japan.

Company Name: **Triton Technology, Inc.**
Address: P.O. Box 99179
San Diego, CA 92169

Area(s) of expertise: Doppler bloodflow meter

Contact Person: Scott Kemper, Pres.
Phone: 800-872-1251 619-272-1251
FAX: 619-272-1451

Company Name: **Universal Sonics Corp.**
Address: 31 Industrial Ave.
Mahwah, NJ 07430

Area(s) of expertise: Contract/custom engineering for major ultrasound OEM's.

employees: 15
yrs in business: 6
\$ annual sales: \$1 M

Contact Person: Ron Hadani
Phone: 201-825-8414
FAX: 201-825-8516

Notes: Most Universal engineers were employed by J&J Ultrasound/Technicare before it was closed in 1986.

Company Name: **Vascular Technology, Inc.**
Address: 25 Industrial Ave.
Chelmsford, MA 01824

employees: 12
yrs in business:
\$ annual sales: \$1 M

Contact Person: Dave Reagan, sales and marketing
Phone: 508-250-0856
FAX: 508-256-1325

Company Name: **Vistec, Inc.**
Address: 17422 Sugar Pine Dr.

Houston, TX 77090

employees: 32
yrs in business: 23
\$ annual sales: \$2 M

Contact Person: Ed Thibaudeau
Phone: 713-444-6128
FAX: 713-444-9474

Company Name: **Waters Medical Systems, Inc.**
Address: 2411 7th Street NW
Rochester, MN 55901

Area(s) of expertise: Doppler cardiac output monitor

employees: 215
yrs in business:
\$ annual sales: \$3 M

Contact Person: Lou Harrold, Dir. Engr.
Phone: 800-426-9877 507-288-7777
FAX: 507-252-3700

Company Name: **Zevex Inc.**
Address: 5175 Greenpine Dr.
Salt Lake City, UT 84123

Area(s) of expertise: Air detector - heart/lung bypass machines

employees: 45
yrs in business: 5
\$ annual sales: \$2.5 M

Contact Person: David J. McNally, VP & Dir. Mktg.
Phone: 801-264-1001
FAX: 801-264-1051



APPENDIX F

Responses to Request to Industry

HOFFREL INSTRUMENTS, INC.

QUESTIONNAIRE

Your name: RUSSEL L. UPHOFF

Telephone #: (203) 866-9205

Your organization: HOFFREL INSTRUMENTS, INC.

1. How many years has your organization been in the ultrasound marketplace? 28
2. How many cumulative engineering person-years of experience does your current staff have in design of medical ultrasound equipment? 46
3. Does your organization have experience in design of battery-operated, medical, ultrasound equipment (Y/N)? No If yes, approximately how many cumulative engineering person-years? _____ However we are presently working on a project of designing and building a battery operated interface unit for operating transducers with the Circadian Scarmate, a battery operated ultrasound unit.
4. Does your organization have experience in design of flight equipment (Y/N)? No If yes, please explain: However our Chief Engineer, Jack Schwarzschild, had such experience with Norden Div. of United Aircraft and Corporate Systems Center of United Aircraft.
5. Does your organization have experience in design of ultrasound equipment specifically for circulating microbubble detection (Y/N)? Yes If yes, please explain: Please refer to the attached advertisement for our transesophageal transducer. One of the major applications of this device is the detection of air emboli.
6. What are your organization's unique strengths in the design of ultrasound equipment? Hoffrel's particular expertise is the design of ultrasound transducers: we have over eighty different models, all designed for medical applications. For years we were the exclusive supplier of such devices for both Philips and Johnson & Johnson. Lately our efforts have been directed towards the design of very small transducers, small enough to fit between the surgeons fingers during various operative procedures. We also design the scanning systems to support these transducer devices.
7. What patents or intellectual property does your organization hold which could be relevant to this project?

U.S. Patents 4,834,102
4,977,898
8. Will your organization be submitting a "Description of Technical Approach" by Friday, November 1, 1991 (Y/N)? Yes

☐

My organization chooses not to submit a response to this request.

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INTRODUCTION

The use of ultrasound to detect gas bubbles in the vascular system is old technology. This can be seen from the attached bibliography with numerous references dating back to 1968, 1969 and the early 1970's. Noteworthy are Maroon's work in neurosurgery, Gillis and Spencer's use for decompression sickness, and Spencer and Simmons' application to cardiac surgery. Before an extensive development program is initiated, it would be well to assemble these papers and use them as a guide in setting up the actual experimental protocol.

Two quite different types of technology have been used for air embolism detection - doppler detectors and imaging systems. Almost surely the final system will be a doppler type because of the ease of miniaturizing this technology. However during the development phase, an imaging system provides unequivocal confirmation of the presence of bubbles. This is important since the ultimate system is going to have to provide some automatic means of recognizing the doppler spectrum produced by bubbles. For this reason the recommended equipment is the Hoffrel Model 518SD which is a duplex system providing both capabilities. Since it displays the doppler spectrum, the development of that essential automatic detector will be facilitated. Fortunately Hoffrel also manufactures a transesophageal transducer which provides views of exquisite clarity of the heart. This has proven to be a useful tool for the anesthesiologist. One of its most important uses is to provide an immediate indication when an operative procedure is introducing air into the vascular system. As such it will provide an invaluable tool in deciding which chamber provides the best indicator of decompression bubble formation. A copy of Hoffrel's advertisement in Anesthesiology magazine is attached. Note the emphasis we place on detection of air emboli.

Neurosurgical Applications

- Grossman BL, Wood EH: Evaluation of cerebrovascular disease utilizing a transcutaneous Doppler technic. *Radiology* 90:586-587, 1968
- Maroon JC, Edmonds-Seal J, Campbell RL: An ultrasonic method for detection air embolism. *J Neurosurg* 31:196-201, 1969
- Maroon JC, Pieroni DW, Campbell RL: Ophthalmosonometry: An ultrasonic method for assessing carotid blood flow. *J Neurosurg* 30:238-246, 1969
- Michenfelder JD, Miller RH, Gronert GA: Evaluation of an ultrasonic device (Doppler) for the diagnosis of venous air embolism. *Anesthesiology* 36:164-167, 1972
- Muller HR: Directional Doppler sonography. A new technique to demonstrate flow reversal in the ophthalmic artery. *Neuroradiology* 3:91-94, 1973
- Spencer MP, Clarke HF: Precordial monitoring of pulmonary gas embolism and decompression bubbles. *Aerospace Med* 43:762-767, 1972
- Spencer MP, Lawrence GH, Thomas GI, et al: The use of ultrasonics in the determination of arterial aeroembolism during open-heart surgery. *Ann Thorac Surg* 8:489-497, 1969

Recent Developments

- Baker DW: Pulsed ultrasonic Doppler blood-flow sensing. *IEEE Trans Sonics Ultrasonics* 17:170-172, 1970

Venous Air Embolism

- Detection of minute venous air emboli with ultrasound. J.C. Maroon, M.D. Dept. of Surgery, Div. of Neurological Surgery, Indiana U. Med Ctr., Indianapolis, Ind. *Surgery, Gynecology & Obstetrics*, pp. 1236-1238. December, 1968.
- Air embolism diagnosed with ultrasound. J. Edmonds-Seal, MD, Nuffield Dept. of Anaesthetics, United Oxford Hospitals, England and J.C. Maroon, M.D. *British Journal of Anaesthesia*, Vol. 24, No. 3, pp. 438-440. July, 1969.
- Evaluation of an ultrasonic device (Doppler) for the diagnosis of venous air embolism. John D. Michenfelder, MD et al., *Anesthesiology*, Vol. 36, No. 2, pp. 164-167. February, 1972.
- Cardiovascular effects of venous air embolism during air and oxygen breathing. Steffoy, Gauger, and Eger, *Anesthesia and Analgesia--Current Researches*, Vol. 53, No. 4, July-August, 1974.

Air Bubble Detection

- In vivo detection of circulating gas emboli associated with decompression sickness using the doppler flowmeter. Gillis, et al. *Nature (British)*, Vol. 217, No. 5132, pp. 965-967. March 9, 1968.
- Detection of gas emboli associated with decompression using the doppler flowmeter. Gillis et al. *Journal of Occupational Medicine*, Vol. 11, No. 3, May, 1969.
- Reprints on the above two from M.F. Gillis, D.V.M. Battelle Northwest, Battelle Memorial Institute, PO Box 999, Richland, Washington.
- The use of ultrasonics in the determination of arterial aeroembolism during open-heart surgery. Spencer, et al. *Thoracic Surgery*, Vol. 8, No. 6, pp. 489-497. December, 1969.
- Development of bubbles in venous and arterial blood during hyperbaric decompression. M.P. Spencer, M.D. *Bulletin of the Mason Clinic*, Vol. 22, No. 1, March, 1968.
- Experiments on decompression bubbles in the circulation using ultrasonic and electromagnetic flowmeters. Spencer, et al. *Virginia Mason Research Ctr., 1000 Seneen Street, Seattle, Washington 98101. Jour. Occupational Med.* Vol. 11, pp. 239-241. May, 1969.
- A doppler flowmeter for detecting air and other emboli. Incorporating a simple method of screening against interference. Carden, E. et al. *Anesthesiology*, Vol. 33, pp. 551-552. November, 1970.
- Microparticle detection during cardiopulmonary bypass. Simmons, Lichtl, Elkanli, Sauer and Almond. *Circulation* 43:1100, Supplement III, October, 1970.
- Detection of microparticles during cardiopulmonary bypass by use of electronic devices. Simmons E. et al. *Mechanical Support for Cardiopulmonary Assistance, Advances in Cardiology*, Vol. 6, April, 1971.

PHASE I

The objective of the initial phase is to determine which vessel or cardiac chamber should be monitored for the formation of decompression bubbles. It is proposed that these experiments be conducted on astronauts in a low pressure chamber at a NASA provided site. In order to complete the phase, NASA personnel will have to be trained to operate the Model 518 including the transesophageal transducer. Charles Tegler, M.D. - Assistant Professor of Neurology at the Bowman Gray School of Medicine - has agreed to act as a consultant in order to provide this function. Dr. Tegler has substantial experience in the use of the Hoffrel 518, in the detection of air emboli and in the use of the Hoffrel transesophageal transducer on awake patients. In this respect it should be noted that in Germany and in some locations in the U.S. transesophageal techniques are used to monitor the heart during exercise tests.

Since Phase I is the only part of the project that needs to be done at low pressures, the doppler spectrum should be monitored during this phase in order to provide information for the automatic detector which must be designed during Phase III.

PHASE II

Once the decision is made as to which chamber or vessel is to be monitored, the project should move into phase II which is the selection or design of a special transducer which can monitor that chamber from a precordial (external) location. Our present thinking is that this would be done by modifying a Hoffrel Model 485(L) transducer. The Model 485 is a scanning transducer designed for intraoperative use which is small enough to fit between the surgeon's fingers. With the Model 518 it can be used for either imaging or doppler. The advantage of this duality is that the image can be used to ensure that the transducer is positioned so that the proper chamber is being viewed. Then a servo system controlled by a cursor is adjusted to bisect the chamber. The Model 518 can then be switched to the doppler mode with full assurance that the proper chamber is being interrogating. It is expected that two modifications of the Model 485 will be required. First, because it will be used externally, the frequency should be lower than the 5.0MHz normally used in the Model 485. This produces the dual advantage of better penetration and a somewhat divergent beam so that the positioning of the transducer becomes less critical. The second modification of the Model 485 would be the provision of a mechanical lock so that the transducer is permanently fixed in its optimal position. In this manner a special transducer is produced for each astronaut in which the doppler beam is ideally positioned for his anatomy.

PHASE III

The objective of phase III is the design of a suitably sized battery operated doppler device suitable for monitoring within the EVA suit. No particular difficulty in this phase is anticipated. The design of the automatic detector referred to previously is obviously an important requirement of this part of the project. Since previous users of air emboli detectors have relied upon auditory recognition of the static, like noise produced by the air emboli, it is anticipated that this recognition process will be suitable for pattern recognition using a microprocessor based system. Our initial plan is to minimize the weight and power consumption by using an ASIC for analog signal processing and a CMOS microprocessor for all control and data handling functions.

PROJECT COST ESTIMATE

I. Phase 1.

A. Duration:	8 months
B. Cost	
1. Labor:	\$59,000
2. Material:	55,000
3. Total:	\$114,000

II. Phase 2.

A. Duration:	4 months
B. Cost:	
1. Labor:	\$32,000
2. Material:	15,000
3. Total:	\$47,000

III. Phase 3.

A. Duration:	6 months
B. Cost	
1. Labor:	\$124,000
2. Material:	21,000
3. Total:	\$145,000

IV. Summary of total program.

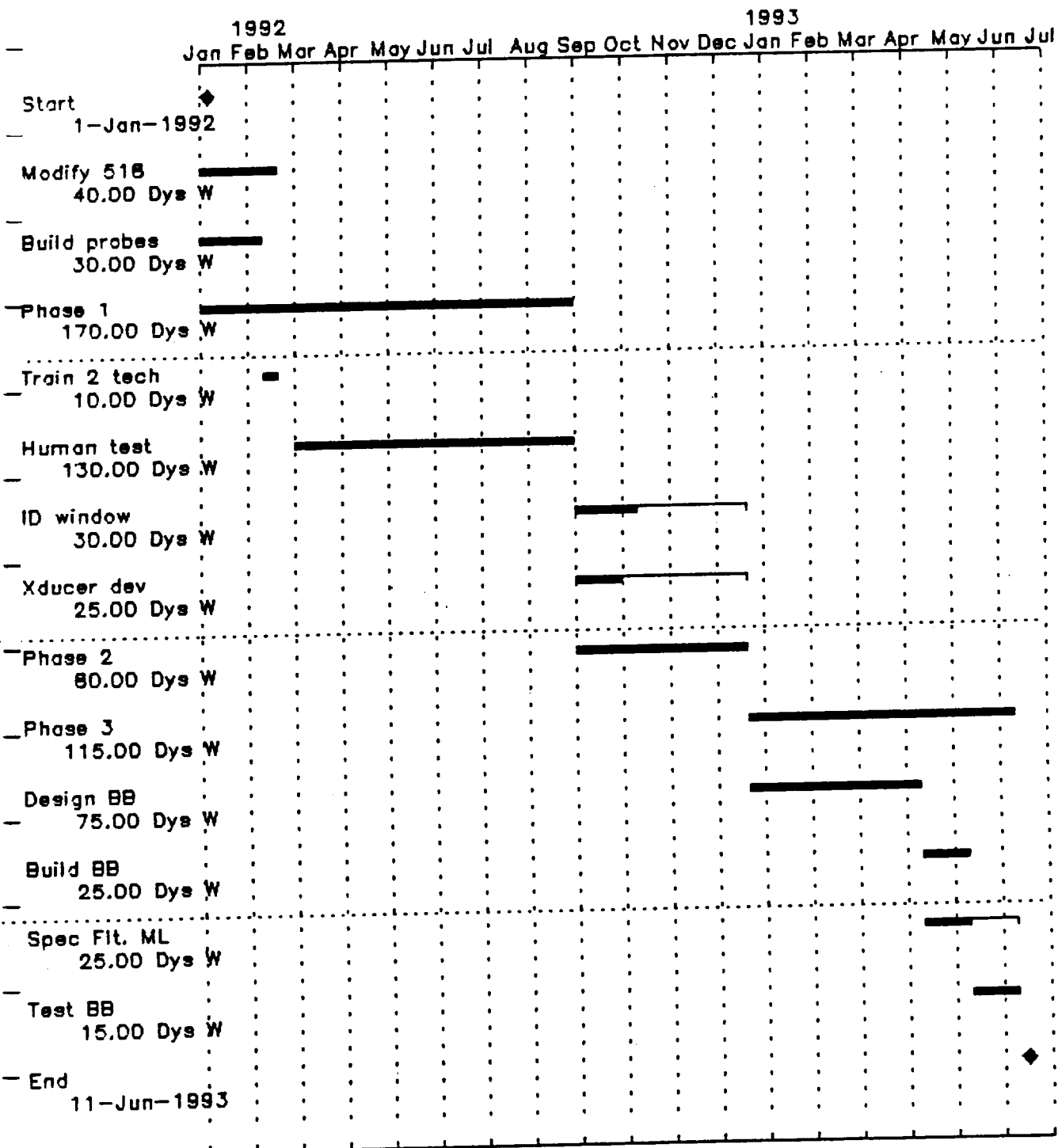
A. Duration:	18 months
B. Cost	\$306,000

zm/russ539

Gantt Chart

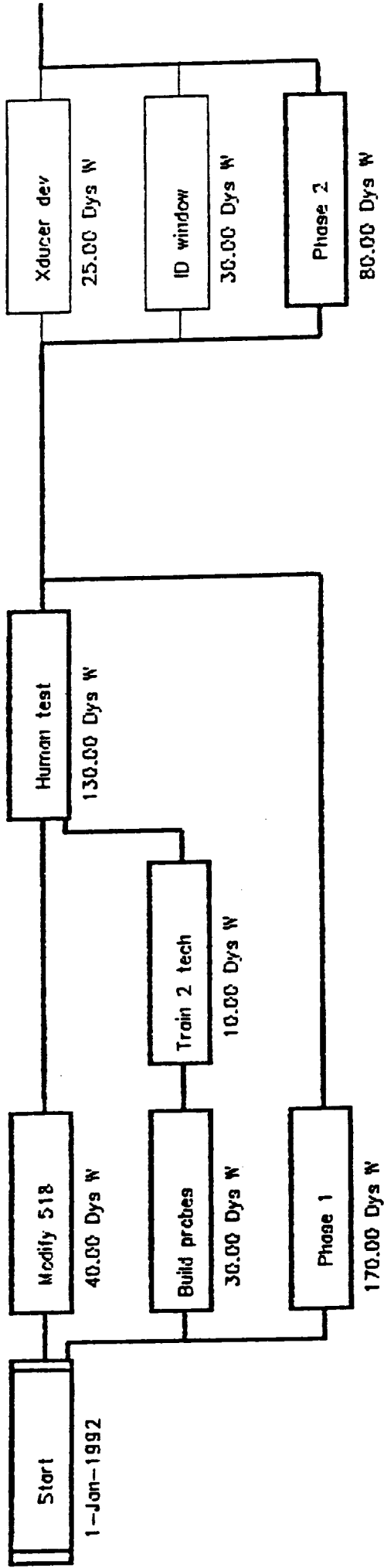
In-Suit Ultrasonic Bubble Detector for EVA
Project: HOFNASA

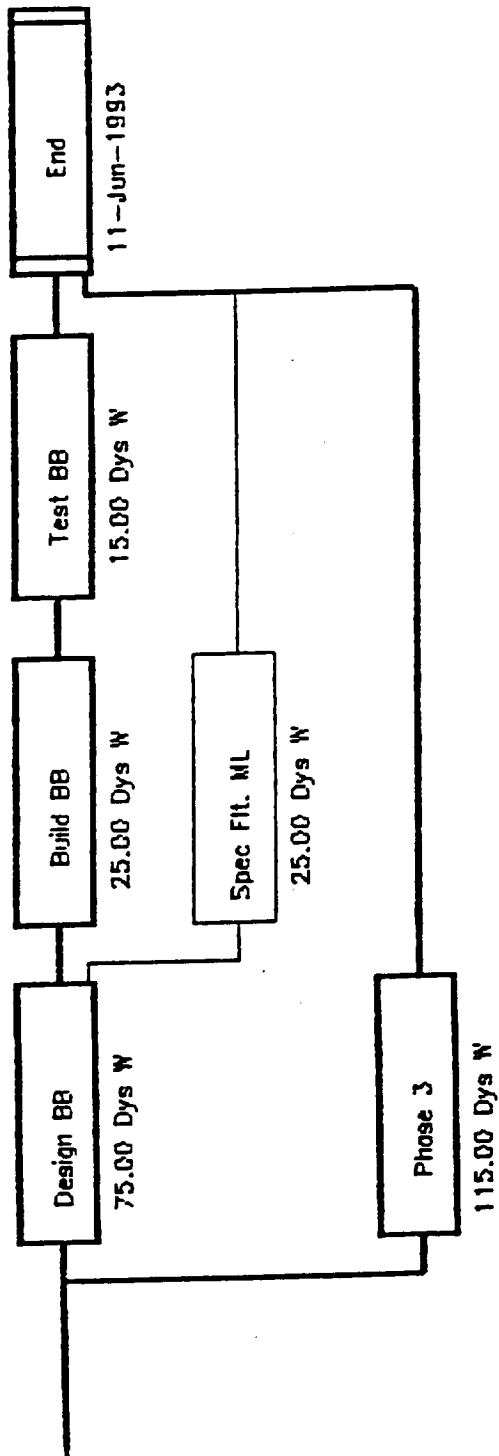
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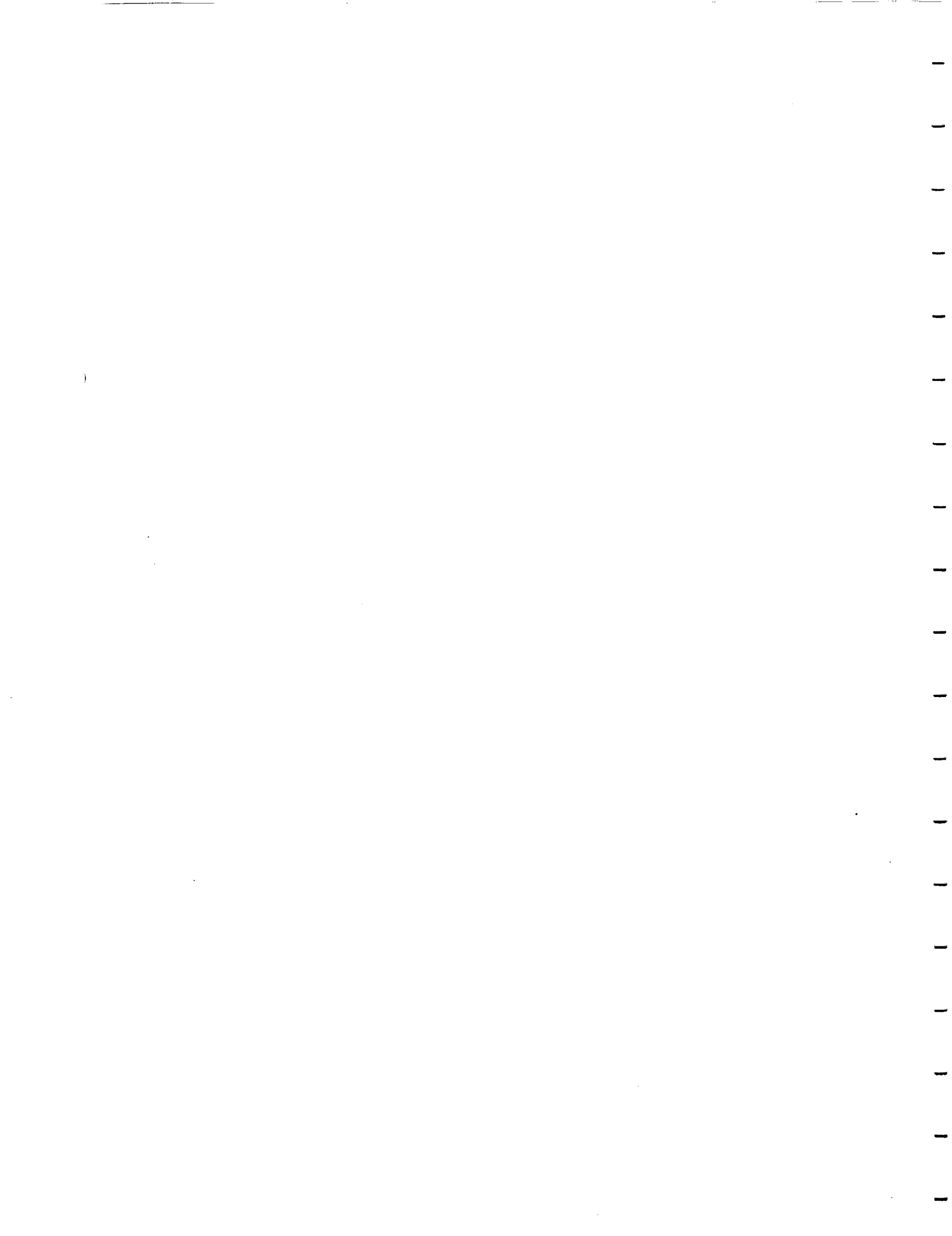


In-Suit Ultrasonic Bubble Detector for EVA
Project: HOFNUSA

PERT Chart







INSTITUTE OF APPLIED PHYSIOLOGY AND MEDICINE

QUESTIONNAIRE

Your name: John R. Klepper, Ph.D. Telephone #: 206/553-7330

Fax 206/553-1717

Your organization: Institute of Applied Physiology
and Medicine

1. How many years has your organization been in the ultrasound marketplace? 20
2. How many cumulative engineering person-years of experience does your current staff have in design of medical ultrasound equipment? 51.5 years in full-time engineering personnel + 1 part-time engineer with 10 years of experience and one physician with 25 years of experience.
3. Does your organization have experience in design of battery-operated, medical, ultrasound equipment (Y/N)? y If yes, approximately how many cumulative engineering person-years? 37
4. Does your organization have experience in design of flight equipment (Y/N)? y
If yes, please explain: Performed a phase I feasibility study for the USAF School of Aerospace Medicine on an in-suit Doppler decompression sickness monitor, contract #F33615-C-83-0618 from August 1, 1983 through July 31, 1984. We have also built and installed transcranial Doppler and associated spectrum analysis equipment for the human centrifuge at USAF SAM.
5. Does your organization have experience in design of ultrasound equipment specifically for circulating microbubble detection (Y/N)? y If yes, please explain: The Institute has marketed Doppler bubble detectors to other research labs since 1971. The ~~Model 1032 is a simple monaural CW Doppler bubble detector sold under the Sound Products Division label since 1971. The Model 1058 is a stereo CW Doppler bubble detector of advanced design sold since 1982.~~ We have also developed a cerebral emboli monitor which detects both bubbles in the cerebral circulation during surgery and formed element emboli passing through the
6. What are your organization's unique strengths in the design of ultrasound equipment? cerebral circulation
The Bioengineering Department of the Institute specializes in ultrasound circulation Doppler instrumentation and signal processing. In addition to CW and pulse Doppler electronics and standard spectrum analysis, the Institute has developed real-time pattern recognition systems for specific vessel identification and emboli detection and quantitation. We have an active hyperbaric medicine program that has done Doppler bubble studies of decompression sickness since 1971.
7. What patents or intellectual property does your organization hold which could be relevant to this project?
1) Proprietary designs for both CW and pulse Doppler electronics.
2) DSP designs for data acquisition, spectrum analysis, and pattern recognition.
3) US Patent #5,052,395 contains pattern recognition techniques possibly of use.
4) A patent application is in process on the cerebral emboli monitor.
8. Will your organization be submitting a "Description of Technical Approach" by Friday, November 1, 1991 (Y/N)? y



My organization chooses not to submit a response to this request.

X

1 A

DESCRIPTION OF TECHNICAL APPROACH FOR AN IN-SUIT ULTRASONIC
BUBBLE DETECTOR FOR EVA

The presence of nitrogen gas bubbles in the pulmonary artery has long been recognized as a possible precursor to the occurrence of bends. Ultrasonic detection of these bubbles using CW Doppler instrumentation has been in practice for some time. However, the results of these exams were generally evaluated subjectively by a trained and experienced observer. Recent technological advances and clinical research in this field indicate that quantitation of the number of bubbles passing through the pulmonary artery is now technologically feasible. We propose a plan to provide an automated real-time identification/quantification system to determine bubble grade in the pulmonary artery.

Key elements in an in-suit bubble detector design are the following:

- 1) Doppler electronics,
- 2) ~~precordial ultrasonic transducer array and controls,~~
- 3) pattern recognition algorithms for identification of pulmonary artery signal,
- 4) pattern recognition algorithms for detection and quantification of numbers of bubbles passing through the pulmonary artery,
- 5) recording and telemetry instrumentation.

Each of these major components will be described below.

~~This system is required to operate in 100 percent oxygen atmosphere at an ambient pressure of 4 PSI.~~ Several constraints result from this requirement. Since fire hazard is the most obvious danger, materials used must not have any volatile or easily flammable components. Electronics must be designed to operate on low voltage, low power, battery operation. Potting of

the electronics must be considered to prevent the possibility of arcing or spark due to static electrical discharge.

1. Doppler Electronics

~~A 2 or 2.5 MHz pulse Doppler is proposed.~~ Much of the published literature on Doppler bubble detection incorporates the use of 5 MHz CW Doppler. From general scattering theory, it appears that such bubbles should be just as easily detectable at 2 to 2.5 MHz. ~~Also, the use of long range-gate pulse Doppler should function just as well as a true CW Doppler.~~ These hypothesis have been essentially confirmed by the recent reports of detection of both bubbles and formed element emboli in the cerebral circulation using 2 MHz transcranial pulse Doppler. We anticipate the use of pulse Doppler to be better than CW for this application since the use of range-gating should significantly reduce the amount of clutter from stationary and slowly moving targets such as heart and vessel walls. A pulse Doppler sample volume will also provide greater bubble-to-blood signal contrast than CW, thereby increasing the detectability of microbubbles.

2. Transducer Array and Controls

A 2-dimensional array of transducers operating in the frequency range of 2 to 2.5 MHz is proposed. The number of transducer elements would need to be determined by computer simulation of beam patterns. ~~Transducer elements would probably number between 9 and 16 in a hexagonal close pack geometry. Transducers would be mounted in a concave low-profile plastic housing and would be designed to cover a broad sample volume of depth range from 5 to 9 cm where the best signal from the pulmonary artery would likely be located.~~ Double quarter wave matching layers would be used with a goal of a round trip insertion loss in the range of 6 to 8 dB. Some existing designs of such transducers are air-backed with an inductive tuning element. The low pressure, 100 percent oxygen environment

requirement might obviate the use of an air-back transducer and require a rigid back instead. ~~It is anticipated that a large number, if not of the all elements would be driven in parallel at a low peak transmit voltage, probably on the order of 1.5 to 3 volts peak-to-peak.~~ Switches would be available to select the operation of each transducer for both transmit and receive. ~~The transducer array needs to span two intercostal spaces in order to ensure that the pulmonary artery signal can be obtained after the hard upper torso of the EVA suit has been put on.~~ An appropriate adhesive material needs to be specified to provide the ultrasonic coupling from array into the body. A likely candidate is the material used for ground return electrodes for electro-surgical apparatus which adheres well to the skin but does not adhere to hair, thereby obviating the need to remove any chest hair from the astronaut.

3. Pattern Recognition for Identifying Pulmonary Artery Signal

The pulmonary artery Doppler waveform can be easily obtained from the precordial position typically using either the second, third, or fourth intercostal space in a short access view. Since individuals undergoing EVA from the space shuttle are ~~typically predetermined~~, it will be possible to positively identify this signal in terms of its normal range-depth and location for each subject as well as identify the characteristic waveform for that subject; all of this being done in routine echocardiographic, ground-based studies. This information can be used to provide an example of the normal pulmonary artery waveform for that particular subject. Barring pathology, this waveform should also be relatively similar from subject to subject. ~~A pattern recognition algorithm based upon the subject's own pulmonary artery waveform measured in ground-based studies could be used.~~ Our approach to the pattern recognition would be to apply Karhunen-Loeve, or principle component analysis to the pulmonary artery velocity profiles obtained in ground-based studies.

We have previously demonstrated this technique in real-time pattern recognition of the aortic Doppler maximum frequency waveform from the ascending aorta. ~~It may be necessary to provide interaction from this pattern recognition algorithm and the algorithm controlling the selection of transducer elements so that it is possible to "lock on" the pulmonary artery signal with a minimum amount of clutter.~~

4. Pattern Recognition for Quantification of Bubbles

We propose to adapt our existing algorithm for identification of embolic signals in the Doppler spectra from the cerebral arterial circulation measured with transcranial Doppler. This is a matched filter approach relying upon the knowledge of the bandwidth and continuity of the Doppler signal from a bubble, denoted by its increased amplitude over the normal background Doppler blood flow signal.

5. Telemetry and Recording Electronics

Several known limitations on the design include the lack of telemetry channels available on the EVA suit and requirement for potential 6-hour duration of operation on a single battery pack. These two constraints point to the likelihood that the eventual package needs to be ~~operated on an intermittent basis.~~ It is desirable to put the minimum amount of electronics necessary within the EVA suit itself. This would include the Doppler electronics, transducer array, battery pack, and a means to store, at least temporarily, a buffer of Doppler data which could be passed to additional processing electronics. ~~These additional electronics would be housed on the support system on the back of the EVA suit.~~ The pattern recognition algorithms would operate on digitally stored data in the support pack. Once the data is processed, it could be modulated over the low frequency end of ~~the voice radio channel to the shuttle.~~ The duty cycle of this intermittent operation is undetermined at this point. Typically

in ground base studies, subjects are monitored briefly for 30 seconds to a minute at 15-minute intervals. Such intermittent monitoring during EVA is practical, resulting in 12 to 24 minutes of full monitoring data in a six hour period.

BUDGET ESTIMATE

Three phases of development are needed:

- 1) A development system with no size constraints to design and test the pattern recognition algorithms and transducer array and controls,
- 2) Reduction of the development system to an operational breadboard system meeting the size requirements,
- 3) Construction of the flight model.

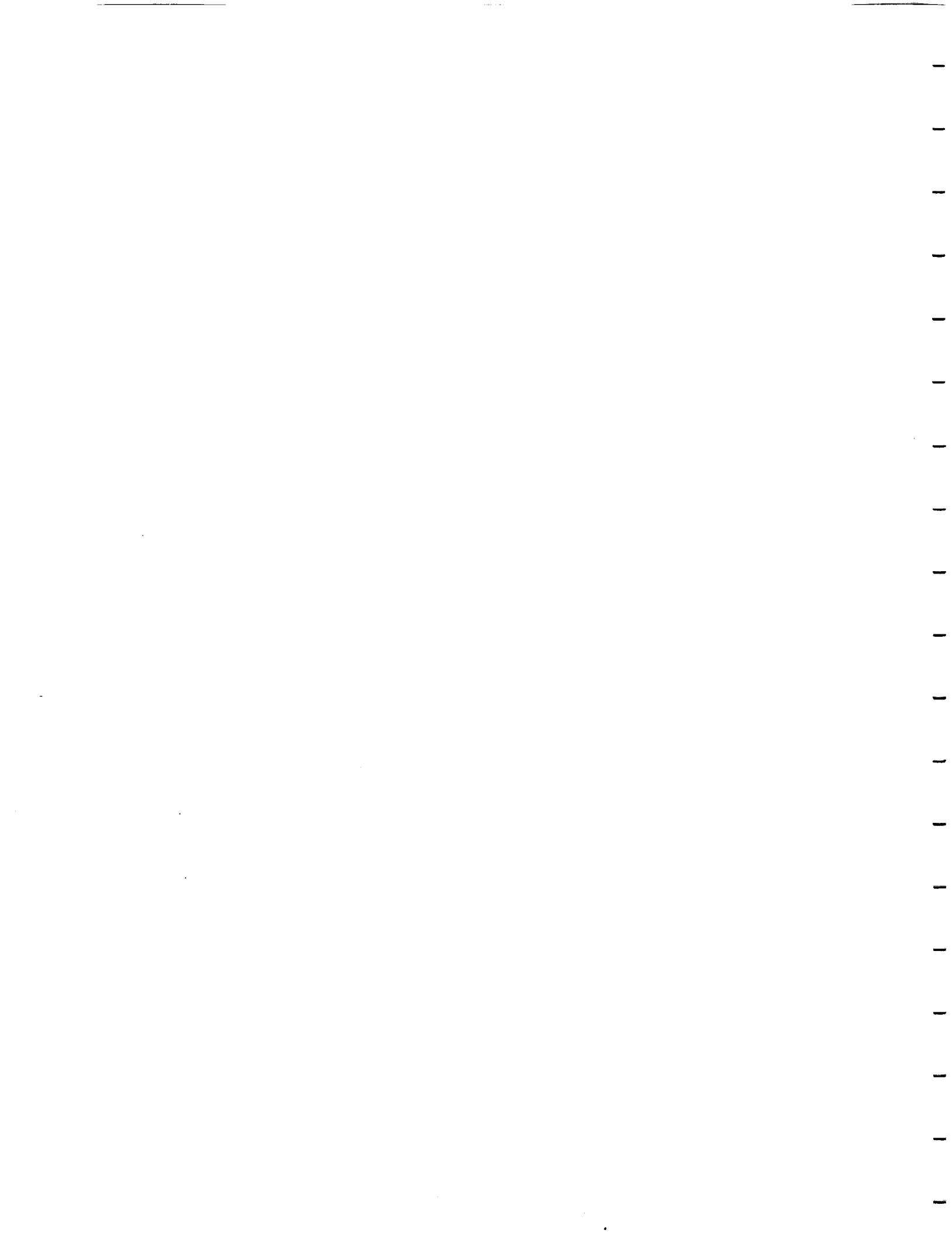
Phase 1 would be accomplished using existing IAPM designs for the pulse Doppler electronics and Digital Signal Processor boards necessary for the pattern recognition development.

Phase 1 is estimated at 8 engineer-months, 2 senior scientist months, and 1 engineer technician month, plus \$20,000 in materials to build 2 working arrays. Labor cost: \$103,700; Total Cost: \$125,000.

Phase 2 is estimated at 24 engineer months, 4 senior scientist-months, and 6 engineering technician months. Total Cost: \$320,000.

Total of Phase 1 and 2: \$445,000.

MEDASONICS, INC.



QUESTIONNAIRE

Your name: (JERRY) George H. Smith, Ph.D. ^{ENGR. MGR.} Telephone #: 415 623-0626

Your organization: MedaSonics, Inc.

1. How many years has your organization been in the ultrasound marketplace? 21
2. How many cumulative engineering person-years of experience does your current staff have in design of medical ultrasound equipment? 18
3. Does your organization have experience in design of battery-operated, medical, ultrasound equipment (Y/N)? Yes If yes, approximately how many cumulative engineering person-years? 3
4. Does your organization have experience in design of flight equipment (Y/N)? Yes
If yes, please explain: Medasonics has delivered transcranial Doppler equipment to NASA for tests in zero-G airplane flights. In addition, the engineering manager, Dr. G. Smith, was employed by McDonnell Douglas Astronautics where he worked with the electromagnetic compatibility group for the Skylab Orbital Workshop in 1972.
5. Does your organization have experience in design of ultrasound equipment specifically for circulating microbubble detection (Y/N)? Yes If yes, please explain:
Medasonics' D-8 Versatone Doppler unit, with its accompanying P81 probe is designed specifically for precordial monitoring for air emboli in the right atrium of the heart during neurosurgical procedures. In addition, a new transcranial doppler system in development will include air/particle embolic event detection as a standard feature.
6. What are your organization's unique strengths in the design of ultrasound equipment?

Medasonics has been manufacturing battery powered ultrasound equipment for medical applications for 21 years.
7. What patents or intellectual property does your organization hold which could be relevant to this project?

Medasonics currently has a patent pending on a method of detecting air/particle embolism which minimizes false alarms due to probe motion artifacts.
8. Will your organization be submitting a "Description of Technical Approach" by Friday, November 1, 1991 (Y/N)? Yes

☐

My organization chooses not to submit a response to this request.

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OF POOR QUALITY

1 A

APPROACH FOR GAS MICROEMBOLUS MONITORING

I. INTRODUCTION

This document provides a brief outline of Medasonics' proposed approach to the microembolus monitoring unit which NASA is considering developing.

Based upon many years of experience with our customers' successful use of the D-8 Versatone CW Doppler unit in the operating room as a monitor for gas emboli in the right atrium of the heart, Medasonics proposes that NASA's system be based upon CW rather than pulsed operation, resulting in significantly simpler electronics, lower power, and higher reliability.

Medasonics submits for consideration several options to the development, ranging from configuring a system from existing components with a custom-designed controller, through developing sensors which would be more resistant to artifact and more easily applied.

II. EXISTING TECHNOLOGY

Medasonics has already developed compact CW Doppler electronics (designated Uniprobe) using thick film technology on a ceramic substrate measuring about .75" x 4" x .5". In addition, Medasonics currently manufactures the P81 probe for detecting bubbles in the right atrium of the heart. This probe, which measures about 1.3" in diameter and about .4" in thickness, is attached using adhesive tape and operates at 2.4 MHz. It has a broad beam profile and is large enough to be quite stable after application. By using this probe, a system could be configured relatively quickly and some preliminary measurements could be made midstream in the development (perhaps on subjects wearing the suit in a vacuum chamber) as a check that the general approach is viable and as a means of limiting the risk of unforeseen problems.

Using the same electronics, Medasonics recommends configuring a neck probe similar in construction to our P94A which consists of a pair of piezoelectric transducers mounted at an angle to the surface of the skin, permitting continuous monitoring of the carotid artery. With this probe, the presence of gas emboli to the brain could be checked, thereby assessing the risk of serious neurological deficit due to embolus formation. Because emboli in the path to the brain could potentially present the greatest risks, Medasonics feels that the small incremental costs in funding and installation time would be a wise investment.

P 1

Medasonics recommends applying self-adhesive sensors consisting of Kynar (tm) piezofilm near to the ultrasound transducers to detect motion artifacts. Medasonics has constructed such sensors for detecting respiratory motion, and the signals from these sensors could be processed to detect periods of vigorous activity which would likely give rise to probe motion artifacts from the ultrasound transducer. The controller would monitor these sensors to squelch or otherwise disqualify the detected ultrasound audio signal.

III. PROBE ARRAY DEVELOPMENT

Medasonics does not recommend developing an array of transducers to automatically find or track the right atrium of the heart or the pulmonary artery. We developed an automated (motor-driven) mount for a pulsed transcranial Doppler unit designed to position a probe to automatically locate, in two axes of translation and two axes of rotation, the signal returned from major arteries in the brain. We found that, although the unit is often able to find its target eventually, the search can be time consuming and was not always successful unless aided by manual intervention. Since positioning the precordial probe involves a two-dimensional search and is relatively easily done by an individual with minimal training, we feel that funds invested for automatic searching on this area would not be wisely spent. If necessary, the proper probe location could be identified and marked on the crew members before flight.

Since the neck probe for monitoring emboli in the carotid artery must be more carefully positioned (due to the smaller cross section of this artery), we propose that an inexpensive linear transducer array be developed to simplify locating this artery. This array would be designed to be self-adhesive rather like a Band-Aid, and could include the Kynar material for motion artifact detection. As mentioned above, the risk of neurological deficit from gas emboli to the brain could pose serious risk to both the crew members' safety and the mission objectives, so providing an index of the level of gas emboli in the carotid artery could be an important component of the system. Furthermore, this is the area that Medasonics feels would hold the highest promise for commercialization, since we believe that monitoring for gas emboli to the brain during cardiac procedures will eventually become a standard of care.

IV. PROPOSED ELECTRONICS

The breadboard would employ Medasonics Uniprobe electronics described above for the CW signal generation and quadrature demodulation, along with switches to select between the precordial probe and the neck probe (or neck probe array elements). A microprocessor would control the RF switches and automatic power down so that the system will be active for

only about 1 minute every ten minutes to conserve battery power. The microprocessor also monitors the Kynar output voltage to reduce artifact. Finally, the microprocessor would digitize and FFT the sampled quadrature data, and use the peaks in the spectrum to further qualify whether strong signal returns are due to bubbles or to probe motion artifact, employing an analysis technique developed at Medasonics. The system output would include the demodulated ultrasound audio signals along with a digital data stream indicating when a bubble has been detected and the sensor which detected the bubble.

V. PROGRAM PHASES AND APPROXIMATE COSTS

This section indicates the proposed phases of the program and makes an initial rough estimate of the cost for the program. These estimates are rough order of magnitude figures based upon the limited information currently available, and are not firm quotes.

Medasonics does not currently manufacture special, limited production devices on a contract basis, and it is not our intention to enter this business. Medasonics' interest in this program is to develop products for which we would own the manufacturing rights and which we could freely market.

Phase I - Concept Demonstration

Configure Medasonics' current P81 probe and a separate P94A angled probe for the neck, each driven by separate Uniprobe electronics, together with Medasonics Cerebrovascular Diagnostic System (CDS) to monitor for gas emboli in tests of the suit in a vacuum chamber. This phase will verify the concept, and will allow convenient test bed for developing any algorithms required, optimizing bubble detection thresholds at various sites, and providing a test fixture and reference for performance comparison against the final delivered breadboard system. Estimated costs are on the order of \$75,000.

Phase II - Neck Probe Array and Compact Electronics

Develop an array transducer for the neck, allowing the transducer with the best carotid artery response to be chosen automatically and incorporating a piezofilm for motion artifact elimination. Concurrently develop compact breadboard electronics that will operate in conjunction with RF switches and existing Medasonics Uniprobe electronics to allow the piezofilm and ultrasound sensor information to be combined and used to generate bubble detection signal output. Estimated costs are on the order of \$250,000.

MEDICAL ACCESSORIES, INC.



QUESTIONNAIRE

Your name: Mr. Janis G. Ziedonis **Telephone #:** 1-609-890-8304
MEDICAL ACCESSORIES, INC.
Your organization: 92 Youngs Rd.
Trenton, N.J. 08619

1. How many years has your organization been in the ultrasound marketplace? 16 years, each key personnel and overall 24 years experience for each key empl.
2. How many cumulative engineering person-years of experience does your current staff have in design of medical ultrasound equipment? 84 years.
3. Does your organization have experience in design of battery-operated, medical, ultrasound equipment (Y/N)? Yes If yes, approximately how many cumulative engineering person-years? 84 We designed battery operated equipment for Hoffmann La Roche for fetal heart detection and for blood pressure measuring equipment and for Medical Accessories, Inc. (our own company) miniature pocket doppler fetal heart detector.
4. Does your organization have experience in design of flight equipment (Y/N)? Limited
If yes, please explain: Our company, Medical Accessories originally worked and developed the equipment and transducers for NASA Space Center to detect the bubbles in the blood stream. The evaluation of the design was done in Houston Tx. Our prototype equipment was never put in actual flight conditions, only in lab testing.
5. Does your organization have experience in design of ultrasound equipment specifically for circulating microbubble detection (Y/N)? Yes If yes, please explain: We developed equipment for Air Emboli that operated at 2 1/2 MHz, clinically used in operating rooms for at least 15 years. Commercially the equipment was known as Embosonde, Model 2000, sold by Roche Medical Electronics. Even today there are some units used in Hospitals.
6. What are your organization's unique strengths in the design of ultrasound equipment?
The key personnel designed ultrasonic equipment for hospitals concentrating on equipment for ultrasonic blood pressure, air emboli, fetal heart rate detection and designing laboratory equipment to simulate the air bubbles, fetal heart motion and blood pressure.
7. What patents or intellectual property does your organization hold which could be relevant to this project? A number of our key personnel have multiple number of Patents in the design of ultrasonic transducers and electronic circuits for medical applications. We have published well over two dozen papers in ultrasonic use of equipment in medical field.
8. Will your organization be submitting a "Description of Technical Approach" by Friday, November 1, 1991 (Y/N)? Yes



My organization chooses not to submit a response to this request.

1A

1.0 Introduction

This proposal outlines in general the technical approach for the design and development of an ultrasonic sensor to detect the presence of intravenous air emboli in the blood stream as it returns to the heart from different body tissues.

The sensor will be designed and developed in a miniature configuration, not to exceed your specified requirements. Since our company originally worked on the concept with NASA personnel in Houston, built preliminary equipment, we still have the miniature multielement transducers and by now have reduced the electronic circuits to hand held probes. By changing the frequency of operation we have the units used for other applications.

Analysis of the bubble wave form and frequency characteristics when illuminated with ultrasound must still be performed. This will simplify the circuit design so it responds mostly to air bubbles and not artifacts or heart beats.

We also designed a special transducer support strap that holds the transducer in place. Also a special vest will be designed to support the electronic package.

After testing, evaluating and acceptance of one miniature prototype by NASA, one flight test unit could be fabricated according to NASA requirements.

2.0 DESCRIPTION OF EFFORT DURING PROTOTYPE PHASE

Our existing miniature electronic circuit will be redesigned and miniaturized so it would meet your requirements and fit easily under the space suit. It is battery operated already. External battery recharging circuit could also be added if necessary.

To obtaining optimum and correct information about the presence air emboli condition in the blood stream, the type of signals received when ultrasound illuminates air bubbles must be identified. Since we already have tape recordings of the air emboli signals from our previous work with NASA on this project, detailed identification and analysis of these signals will be performed. Knowing the wave form and frequency of the signals will permit to redesign the circuit that will respond to these type of signals more effectively without using human ear as a reference and record them when they occur. Once this has been accomplished an alarm system could be added, not

part of this proposal, to alarm the individual of presence of air emboli condition in the blood stream.

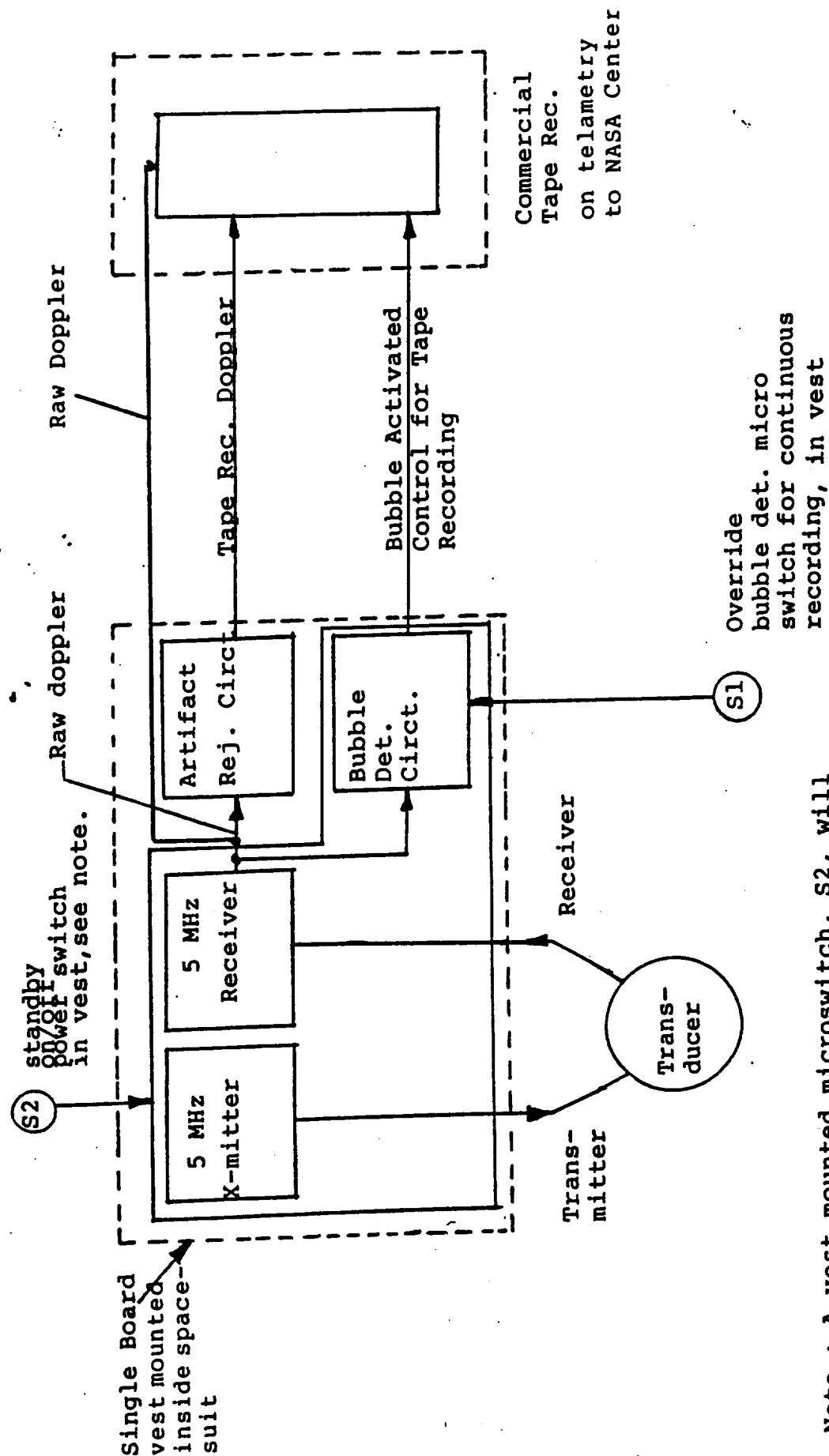
- 2.1 MAI will rent a special high speed waveform analyzer equipment that will capture and record the air emboli signal waveform and frequency. Once the signals have been identified, miniature circuit will be designed that responds primarily to the air emboli.
- 2.2 Physically a miniature 5 MHz battery operated transmitter-receiver circuit will be built to operate the transducer, detect the air emboli signals with the artifact rejection circuit.
- 2.3 MAI will perform in house testing for acceptability and performance of the new circuit using our previously designed bubble generating system and the tapes that we have from our previous contract on this project. Then with MAI's personnel at NASA we will help to operate and evaluate the system in simulated conditions in altitude chamber. The prototype circuit will be packaged close in design and size to the final unit to be delivered to NASA.

3.0 Transducer and It's Support Design.

A new thin 5 MHz ultrasonic transducer will be designed that will snap on a U-shaped transducer support bracket. This bracket will fit on individual's chest and hold the transducer at the preselected area during the monitoring and exercise period. The U-shaped bracket will provide the necessary continuous pressure on the ultrasonic transducer so a technician does not have to hold it in place during tests. This U-shaped bracket is separate from the vest that would be used to hold the electronic circuit.

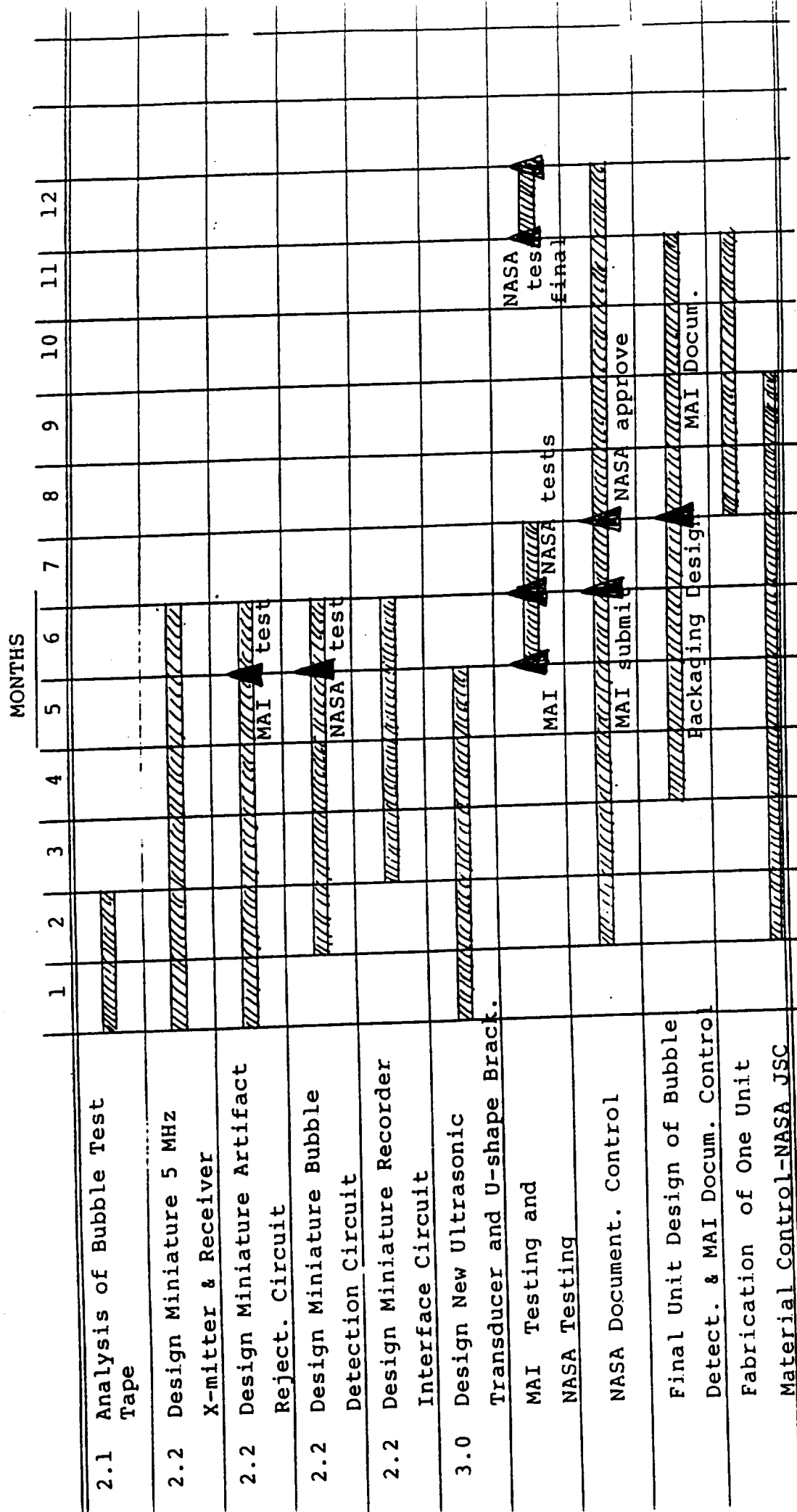
- 4.0 Since there are many different design techniques that could be used for detecting the air emboli, one approach is shown in Fig. 1. As additional detailed information is obtained this design could be changed to achieve optimum information and performance. A possible time table that could apply to this project is shown in Fig. 2.
- 5.0 The approximate cost for developing the prototypesystem, including special test equipment rental, redesigning the circuit, designing artifact rejection circuit, transducer design, special transducer support strap design, EMI proof housing design, lab testing and evaluation of the equipment at NASA Space Center would be approximately \$ 130,000. range.

Fig. 1 BLOCK DIAGRAM OF THE PROPOSED AIR EMBOLI DETECTION SYSTEM



Note: A vest mounted microswitch, S2, will allow standby on/off power to be used as desired.

FIG. 2 A 12 MONTH SCHEDULE FOR THE DEVELOPMENT OF THE IN-SUIT BUBBLE DETECTOR



OXFORD/SONICAID

QUESTIONNAIRE

011

Your name:

JOHN L. FRANCIS

Telephone #: 0235 533433 (UK)

Your organization:

OXFORD SONICAIN

1. How many years has your organization been in the ultrasound marketplace? 20
2. How many cumulative engineering person-years of experience does your current staff have in design of medical ultrasound equipment? 50
3. Does your organization have experience in design of battery-operated, medical, ultrasound equipment (Y/N)? Y If yes, approximately how many cumulative engineering person-years? 20
4. Does your organization have experience in design of flight equipment (Y/N)? N
If yes, please explain:
5. Does your organization have experience in design of ultrasound equipment specifically for circulating microbubble detection (Y/N)? Y If yes, please explain:
WE HAVE SOLD SPECIAL VERSIONS OF OUR EQUIPMENT FOR THE DETECTION OF AIR EMBOLI IN HUMANS.
6. What are your organization's unique strengths in the design of ultrasound equipment?
RELEVANT STRENGTHS ARE THE DESIGN OF MULTICRYSTAL WIDE ANGLE U/S TRANSDUCERS AND ASSOCIATED SIGNAL PROCESSING
7. What patents or intellectual property does your organization hold which could be relevant to this project?
DESIGN RIGHTS ON LOW NOISE ANALOGUE RF CIRCUITS
COPYRIGHT ON SOFTWARE ALGORITHMS FOR U/S SIGNAL PROCESSING.
8. Will your organization be submitting a "Description of Technical Approach" by Friday, November 1, 1991 (Y/N)? Y



My organization chooses not to submit a response to this request.

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1A

STAGE A

Objective

To produce an instrument that would enable the concept of an ambulatory microbubble detector to be evaluated. The instrument would be suitable for ground based clinical trials and for bench performance characterisation.

Requirements

1. Transducer to site interface.

We would supply an existing multi-crystal, wide angle, low profile ultrasound transducer. This can be glued to the chest using adhesive ultrasound coupling glue, however we would recommend attachment by means of a special purpose buckle and belting which has been proven in both supine and ambulatory work.

2. Artifact Rejection

The Stage A instruments would enable ambulatory artifact to be assessed. Experience has shown that gas bubbles above a certain size give a characteristic pattern to the frequency envelope of the reflected signal. Below this size, their reflections may be indistinguishable from those of red blood cells. Digital signal processing techniques would enable the characteristic signal to be extracted from moderate levels of ambulatory noise. An additional source of artifact may arise from the cooling garment if the water used is not pure and degassed.

3. Dynamic Range

No additional work is envisaged here. We have specific expertise in maximising dynamic range for all our ultrasound products including blood flow analysers and fetal heart detectors.

4 Transducer size

See 1. above. The wide angle transducer would enable full trials to be conducted and may be suitable for the final application.

5 Power

The existing instrument has a four hour battery capacity. This would be increased to 6 hours with little difficulty for the Stage A units.

6. Weight

The existing instrument would be repackaged to meet the weight limitation. This would not involve technical risk.

7 Volume

Repackaging would achieve the required volume, again without technical risk.

8. Operating Temperature.

The operating temperature range is exceeded by the existing instrument.

9. Operating atmosphere.

All our instruments are designed to meet international medical safety standards including UL544 and IEC601. Additional requirements for intrinsic safety would need to be specified and taken into account in repackaging.

Tasks Required

The tasks required to achieve the above requirements are not considered to involve significant technical risk. The Stage A instruments would be based on existing technology with some circuit changes and repackaging. We would estimate the design changes to cost approximately \$40,000 and the unit cost to be in the region of \$5,000. Thus three Stage A prototypes (the practical minimum) would involve a total cost of about \$55,000. Delivery would be within 20 weeks from placement of order.

Trials, Performance Characterisation and Further Development.

We would consider the above to be an essential precursor to the bench testing and trials which would be necessary to test the concept and develop the final product.

Ethical and practical problems in running human trials involving gas microbubbles call for the use of bench modelling where possible. Air bubbles could be injected into artificial blood circulating in a phantom. The size and quantity of bubbles could be determined by optical or other means and correlated with the instrument output. A digital signal processor would sample the output and the sensitivity of the algorithms would be adjusted to detect the required level of bubble activity. Ambulatory human trials on normal subjects, without gas bubbles, would enable the algorithms to be tested for false positives and adjusted if necessary.

Following this work the system would be ready for vacuum chamber trials which would presumably be under NASA control. The results of these would enable the final product, Stage B, to be designed.

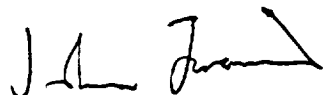
Sonicaid Products

Summary

Stage A equipment could be provided with little technical risk. This would enable the concept to be tested and the final product developed.

I hope this assessment meets your requirements, and I look forward to hearing from you.

Yours sincerely,

A handwritten signature in black ink, appearing to read "John L. Francis". The signature is fluid and cursive, with a long horizontal stroke at the end.

John L. Francis

R & D Manager.

TECHNO SCIENTIFIC, INC.

QUESTIONNAIREYour name: DR. MIREK MACECEKTelephone #: (416) 851-9958Fax: (416) 851-6314Your organization: TECHNO SCIENTIFIC INC.

1. How many years has your organization been in the ultrasound marketplace? 10
2. How many cumulative engineering person-years of experience does your current staff have in design of medical ultrasound equipment? 20
3. Does your organization have experience in design of battery-operated, medical, ultrasound equipment (Y/N)? Y If yes, approximately how many cumulative engineering person-years? 3
4. Does your organization have experience in design of flight equipment (Y/N)? Y
If yes, please explain:
WE HAVE GAINED SOME EXPERIENCE IN THIS AREA THROUGH PREVIOUS CONTRACTS WITH NASA AND DCIEM (DEFENCE CIVIL INSTITUTE OF ENVIRONMENTAL MEDICINE) FOR THE SAME SUBJECT. WE ALSO HAVE THE CLOSE COOPERATION OF TORONTO-BASED SPAR AEROSPACE WHO ARE THE SUPPLIERS OF THE SPACE ARM FOR EVA.
5. Does your organization have experience in design of ultrasound equipment specifically for circulating microbubble detection (Y/N)? Y If yes, please explain: WE BELIEVE TSI IS STILL THE ONLY MANUFACTURER (INTERNATIONALLY) OF THIS INSTRUMENT. WE HAVE GAINED EXTENSIVE EXPERIENCE THROUGH SEVERAL MODIFICATIONS OF THE UNIT FOR DIVERS, PILOTS & ASTRONAUTS. SEE DOPPLER BROCHURE AND PHOTOGRAPH IN COMPANY PROFILE.
6. What are your organization's unique strengths in the design of ultrasound equipment?
TSI'S STRENGTHS LIE IN EXTENSIVE TRANSDUCER DESIGN CAPABILITIES, COMPLETE ELECTRONIC DESIGN INCLUDING PADS, ORCAD AND OTHER SOFTWARE SCHEMES AS WELL AS SOFTWARE AND COMPUTER SUPPORT. WE ALSO ARE ACTIVE IN ULTRASONIC NOT INSTRUMENT DESIGN & MANUFACTURE.
7. What patents or intellectual property does your organization hold which could be relevant to this project?
WE HAVE AN EXCLUSIVE LICENSE FROM THE DEPT. OF DEFENCE IN CANADA ON PRODUCTION OF THE UNITS FOR DOPPLER BUBBLE MONITORING BASED ON OUR RESEARCH FOR THEM.
8. Will your organization be submitting a "Description of Technical Approach" by Friday, November 1, 1991 (Y/N)? Y



My organization chooses not to submit a response to this request.

A.

TECHNICAL APPROACH TO AN
"IN-SUIT ULTRASONIC DOPPLER BUBBLE DETECTOR"

Introduction

Techno Scientific Inc. (TSI) was contacted by LSR Incorporated to submit a "white paper" on our technical approach to the development of an "In-Suit Ultrasonic Doppler Bubble Detector for EVA".

TSI responds with a brief description of the DBM9008, an ultrasonic doppler bubble monitor designed and manufactured by TSI and the DBM9008i, an in-suit version of the DBM9008 developed for both NASA and DCIEM (Canadian Defence and Civil Institute of Environmental Medicine). Also included is a section outlining the modifications to our existing equipment that will be necessary to meet your specified requirements.

Technical Description of the DBM9008 and DBM9008i

The operation of TSI's current Ultrasonic Doppler Bubble Monitor is based on the Doppler effect on an ultrasonic wave transmitted into and reflected from anything in motion below the skin surface. Bubbles are detected by monitoring the ultrasonic signals reflected from the blood stream and by listening to and classifying these signals. This reflected signal contains information about the gas bubble content as well as the blood flow rate. The blood flow and heart beat are clearly audible.

Our existing DBM9008 utilizes a 2.5 MHz ultrasonic transducer in CW mode to detect the presence of gas bubbles in the bloodstream. TSI has received the best signal response from placement in the precordial region. The optimal focal length for this region is found to be 7cm. The existing electronics consist of a transmitter, an analogue receiver/demodulator and various filters to provide audible recognition of bubble flow.

The unit has an automatic gain monitoring circuit to prevent distortion when the heartbeat occurs and provide enough gain to detect μ size bubbles. It is powered by a 9V cell and lasts approximately 10 hours. Control signals are available to record the output of the unit and predefined intervals for a preset time.

To measure the blood bubble content, a transducer is placed against one of three possible body sites (the precordium or one of the subclavian veins) of the subject being tested. A harmless gel is used as a coupling agent between the subject's skin and the probe surface. A continuous wave ultrasonic signal is transmitted and the reflected ultrasonic signal is received and processed by the system's electronics.

The signal output can be listened to by an operator using headphones or by recording it on a standard cassette unit for playback at a later time. The existing concept requires training to teach the user or operator to recognize the sound of the bubbles.

The DBM9008i utilizes a smaller transducer, with approximate outer dimension of 2cm X 3cm, a smaller enclosure for the electronics and a self-contained tape recorder. Except for the size restrictions, this unit matches very closely the unit specified in the LSR requirements.

Modification Requirements

Transducer

The current transducer design will be modified to accommodate low profile and interface specifications. TSI has already investigated several methods to adhere the unit to the chest and will experiment with these to select the optimal method based on use in space, range of movement and clothing restrictions. The possibility of a self-coupled transducer head will be investigated.

We are not sure that the array approach outlined in the LSR block diagram is necessary or that it indeed will be beneficial. We also are convinced that CW mode as opposed to pulse operation mode is superior as bubbles can be missed through continuous switching. This is based on previous research.

Operating atmosphere

TSI will ensure that the unit(s) contain no exposed wiring that will be affected by the oxygen atmosphere. Our previous experience with NASA revealed that the recording medium presented a major safety risk because of the oxygen environment. It was concluded that no moveable parts or any part that could cause sparking should be used in the design and additional precautionary measures should be considered.

Electronic components

The LSR block diagram showing the potential configuration for the unit indicates the use of an A/D converter for feedback to the microprocessor controller. The question to be answered is whether the output signal for the processor should be digitized. We do not think that on-site processing is necessary or required but by using telemetry, the original signal could be enhanced and evaluated outside the space suit. For telemetry transmission, the digitization of the signal will be beneficial.

Flight model from prototype

Once the "Breadboard" design has been finalized, TSI will develop the "Flight Model" which requires miniaturization of the prototype and definition of connections, seals and packaging. The major effort will be in the miniaturization, safety tests and approvals.

Rough order-of-magnitude price

TSI estimates the cost (in \$U.S.) of developing a state-of-the-art operational prototype to be \$40,000 to \$60,000 and telemetry \$15,000 to \$20,000. EVA testing to be carried out by TSI and/or NASA will require another effort of \$20,000 to \$40,000.

List of purchasers of the DBM9008

Following are only some of the institutions and organizations which have purchased one or more of TSI's Ultrasonic Doppler Bubble Monitors:

- DCIEM
- NASA
- U.S. Navy
- Royal Netherlands Navy
- Royal Australian Navy
- Schmidt Scientific Taiwan Ltd.
- Naval Experimental Diving Unit, U.S.
- Virginia Mason Hospital
- Pearls Pty. Ltd., Australia
- West Indies Laboratory
- The following U.S. Universities:
Concordia, Michigan, New Hampshire, Duke, Pennsylvania,
North Carolina, Florida State, Texas

UNIVERSAL SONICS CORP.

QUESTIONNAIRE

Your name: Ron Hadani

Telephone #: 201 825-8414

Your organization: Universal Sonics Corp.

1. How many years has your organization been in the ultrasound marketplace? 6 years.

2. How many cumulative engineering person-years of experience does your current staff have in design of medical ultrasound equipment? 98 years.

3. Does your organization have experience in design of battery-operated, medical, ultrasound equipment (Y/N)? Yes. If yes, approximately how many cumulative engineering person-years? 2 years.

4. Does your organization have experience in design of flight equipment (Y/N)? Yes. If yes, explain:

Due to an arrangement for the exchange of engineers and scientists with RAFAEL, the Armament Development Authority of ISRAEL, Universal Sonics has employees with ten to twenty years of experience in the development of miniaturized and ruggedized flight equipment.

5. Does your organization have experience in design of ultrasound equipment specifically for circulating microbubble detection (Y/N)? Yes. If yes, please explain:

Universal Sonics has broad expertise in the design and development of state of the art ultrasound systems. As a supplier to many of the OEM's in the ultrasound field, we provide subassemblies such as a Doppler modules, Doppler Color Flow modules, ultrasound pulser/ receivers, Cine loop boards, Beamformers etc., as well as complete imaging systems and cardiac patient monitoring equipment.

6. What are your organization's unique strengths in the design of ultrasound equipment?

Universal Sonics Corporation has broad expertise in the design and development of state of the art ultrasound systems. As a supplier to OEM's we provide subassemblies, such as Doppler modules, Doppler color flow modules, ultrasound pulser/ receivers, Cine loop boards etc., as well as complete imaging systems. Universal Sonics has also developed patient monitoring equipment.

7. What patents or intellectual property does your organization hold which could be relevant to this project?

A unique miniature pulser, capable of delivering 300 volts with a 10 nanosecond risetime.

Expertise in Cardiac output monitoring gained from the development of such a monitor based on a CW Doppler with probes monitoring the ascending aorta through the suprasternal notch and the descending aorta using a trans-esophageal probe.

A compact low noise CW/PW Doppler operating over the 2MHz to 10 MHz frequency range.

A unique Doppler Range-Gate Integrator design for improved Signal to Noise in Doppler Color Flow front-end.

8. Will your organization be submitting a "Description of Technical Approach" by Friday, November 1, 1991 (Y/N)?

Yes

IN-SUIT ULTRASOUND BUBBLE DETECTOR FOR EVA
DESCRIPTION OF TECHNICAL APPROACH

1. General -

Universal Sonics Corp. will develop a small, battery operated Doppler ultrasound based instrument capable of monitoring micro-sized bubble activity in the blood flow of an astronaut in a space suit. Once configured, the instrument will operate unattended during EVA.

The system will consist of a low-profile, small array of transducers and a Doppler Ultrasound Unit (DUU) which will be located inside the space suit. The acquired information will be telemetered to the space vehicle to the Doppler Processing Unit (DPU). To minimize power consumption and data storage requirements, data will be sampled for 10 to 20 seconds every several minutes. The information will be stored in memory for future analysis in the DPU.

2. Development Program -

Universal will divide the development program into three (3) phases:

- Feasibility studies
- Breadboard design
- Flight model design

2.1 Phase 1 - Feasibility studies

During this phase Universal will identify, test and evaluate the following:

- * The best monitoring sites and transducer mounting methods for these sites.
- * The optimal operating frequency to maximize microbubble sensitivity and minimize motion artifacts.
- * Define telemetry method to be used.
- * Define storage method to be used.
- * Validate feasibility of meeting packaging and power requirements of flight model.

2.2 Phase 2 - Breadboard design

During this phase Universal is planning to design and develop a functional breadboard. The breadboard will be the electrical equivalent of the flight model, but will not meet the environmental, packaging and power requirements. However, the design approach will reflect the constraints of the flight model specifications wherever possible.

2.3 Phase 3 - Flight model design

During this phase, Universal will develop the flight model. The verified and approved circuitry of the breadboard version will be redesigned and reimplemented to meet the requirements of the flight model. This version will require the use of surface mount and custom I.C.'s to meet the packaging and power requirements (i.e. volume, weight, temperature, atmosphere etc.).

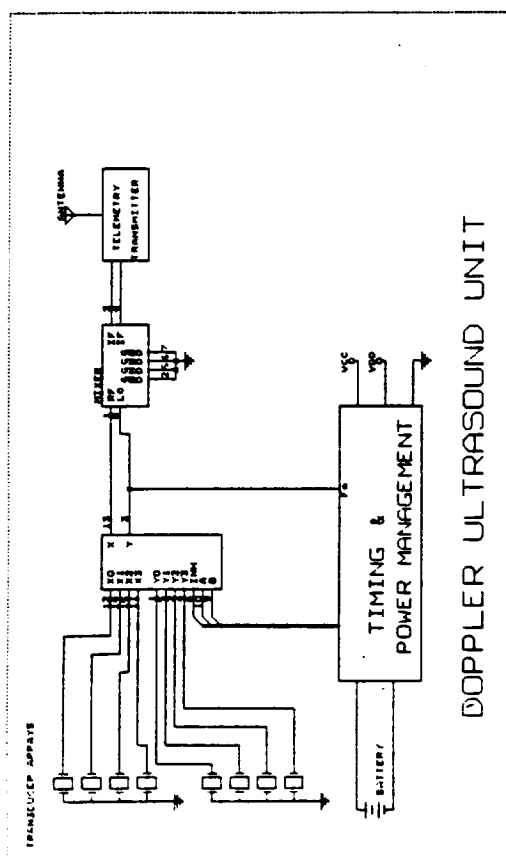
3. General technical approach -

Universal's approach will be based on a ~~CW continuous wave Doppler~~ ~~continuous wave Doppler~~. An array of split transducers will be mounted inside the astronaut's space suit aiming towards the monitored sites. The front end of this Doppler will be based upon Universal's existing technology. The transducers will be multiplexed sequentially and the audio output of each site will be telemetered to the DPU for analysis and storage. A processor in the DPU will analyze the data and record the time, location and occurrence of the bubbles, while rejecting signals from body motion.

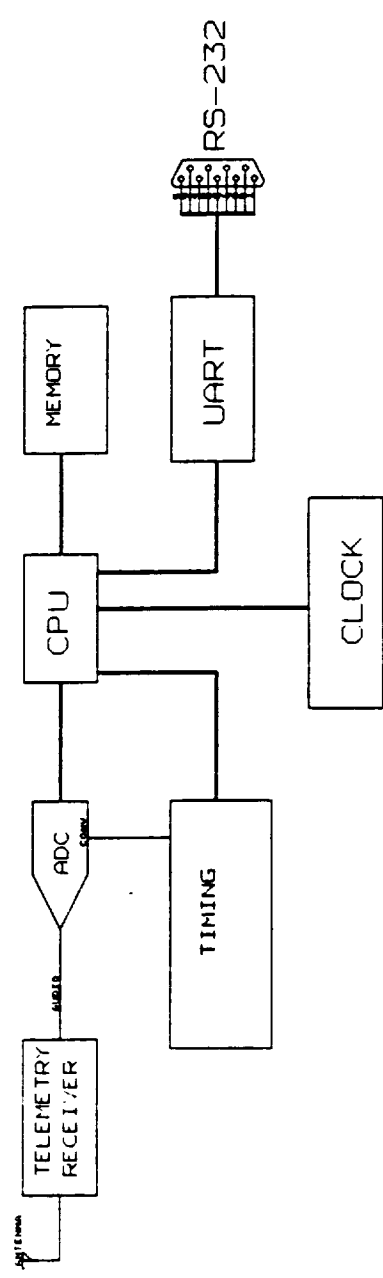
4. Estimated development charges -

The following are Universal's budgetary estimates for the development time and charges:

Feasibility studies: 3 months	\$100,000
Breadboard development: 9 months	\$350,000



IN SUIT



DOPPLER PROCESSING UNIT

UNIVERSAL SONICS CORPORATION	DATE	REVISION	BY	CHKD
21 Industrial Ave.				
Bedford, MA 01730				
Phone: (508) 833-8814				
Fax: (508) 833-8814				
IN SUIT SAMPLE DETECTION				
HYDROGRAPHIC SURVEY				
FILE				

NOTES: All calculations are in base units unless otherwise specified.



APPENDIX G

Sample Ultrasound Transducer Patent (Abstract)



004279543 WPI Acc No: 85-106421/18

XRPX Acc No: N85-079779

Two-dimensional transducer array for ultrasound imaging provides selective actuation of discrete element in planar array of elements separated from each other acoustically and electrically; DOPPLER BLOOD FLOW MEASURE MEDICAL DIAGNOSE

Index Terms: TWO-DIMENSIONAL TRANSDUCER ARRAY ULTRASONIC IMAGE; SELECT ACTUATE DISCRETE ELEMENT PLANE ARRAY ELEMENT SEPARATE ACOUSTIC ELECTRIC

Patent Assignee: (GENE) GENERAL ELECTRIC CO
Author (inventor): BRISKKEN A F

Number of Patents: 004

Patent Family:

CC Number	Kind	Date	Week	
EP 139285	A	850502	8518	(Basic)
US 4530363	A	850723	8532	
EP 139285	B	901227	9101	
DE 3483868	G	910207	9107	

Priority Data (CC,No,Date): US 543945 (831020);

Applications (CC,No,Date): EP 84112277 (841012);

EP and/or WO Language: English

EP and/or WO Cited Patents:

A3...8705; GB 2005835; US 4307613; US 4062237; US 4067236; US 4242912;
DE 2643918; US 4203162; 4.Jnl.REF; US 3888238; 1.Jnl.REF

Designated States (Regional): DE; NL

Abstract (Basic): EP 139285

Sixty-one piezo-electric transducer elements (1-61) are provided on the surface of a support member (152). A respective conductive lead from each element connects through a cable (153) with the ultrasonic system. By selection of the sequence of energisation of the channels (1-61) for transmission, the acoustic beam is steered as required in a direction disposed transversely of the surface. Similarly the sequence of energisation of the elements for receiving an echo signal is scanned as desired.

In a far-field application the array is energised to provide a number of concentric annuli with the degree of focussing being dependent on the number of annuli defined.

USE/ADVANTAGE - For non-invasive measurement of flow rate in blood vessels at various depths in body tissue. Array can be operated in sector scan mode and in focussed or unfocussed mode. Focussed array has a widely-variable focal length. @(15pp Dwg.No.5/8)@

Abstract (US): 8532 US 4530363

A two dimensional transducer array includes a number of discrete transducer elements in a planar pattern. Each element is electrically and acoustically separated from others. The elements are selectively actuated in one mode as a linear transducer array for sector scanning and locating a vessel of interest.

The elements are selectively actuated in a second mode as several annular arrays for far field focussing on the vessel for blood flow measurements. The elements are actuated in a third mode as a central disc and an outer annulus for near field focussing on the vessel for

blood flow measurements.

ADVANTAGE - Transducer array has widely variable focal length.
@ (8pp) @

Abstract (EP): 9101 EP 139285

Ultrasonic apparatus for measuring blood flow in a vessel comprising a two dimensional array of ultrasound transducer elements (151) arranged in rows and columns on a plane surface of a support member (152), said elements being electrically and acoustically separated from each other, means for energising selected ones of said transducer elements in a predetermined sequence so as to transmit ultrasonic energy into the vessel and to receive ultrasound echo signals from the vessel, the apparatus, being characterised in that the means for energising are arranged to provide any of the following operating modes: (i) a sector scan mode, in which the transducer elements are selected to form a linear array of groups of elements which groups are excited successively so as to provide a sector scan enabling location of a vessel to be measured, (ii) a near field Doppler mode, in which either the transducer elements of a disc area or the elements of this area together with those of an annular area concentrically surrounding said disc area are excited simultaneously so as to form alternately a narrow beam and a wide beam intercepting a part or the whole of the vessel cross section, respectively, and (iii) a far field mode involving the simultaneous excitation of the transducer elements in each of a plurality of separate areas of said two dimensional array, said areas comprising an inner disc area and a plurality of annular areas concentrically surrounding said disc area, the areas being excited successively so as to provide a beam focused on said blood vessel. @ (11pp) @

File Segment: EPI

Derwent Class: S05; V06; W06; P86; R19; P31

Int Pat Class: G01S-015/89; G10K-011/34; A61B-010/00

Manual Codes (EPI/S-X): S05-D01B1; S05-D03; V06-B03; V06-H; W06-A05

APPENDIX H

Sample Manufacturers' Literature



Air Emboli Detector D206E



*A sensitive ultrasonic method for
diagnosing and monitoring venous air embolism—
a potentially fatal complication, occurring
during neurosurgical procedures performed
in the upright position.*

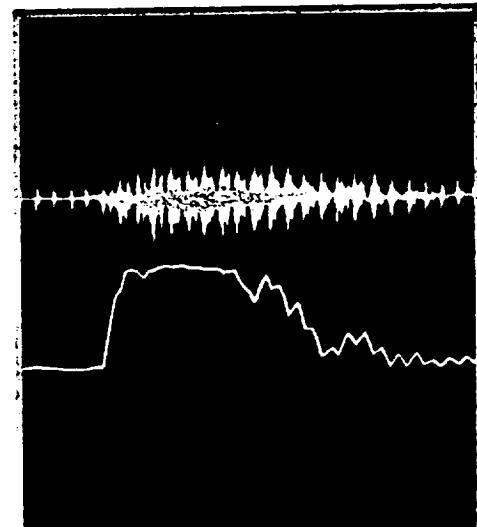


**Recorder output responding
only to the presence of
air embolism.**

**Wide angle multi-crystal
monitoring transducer.**

**Electrocautery interference
rejection.**

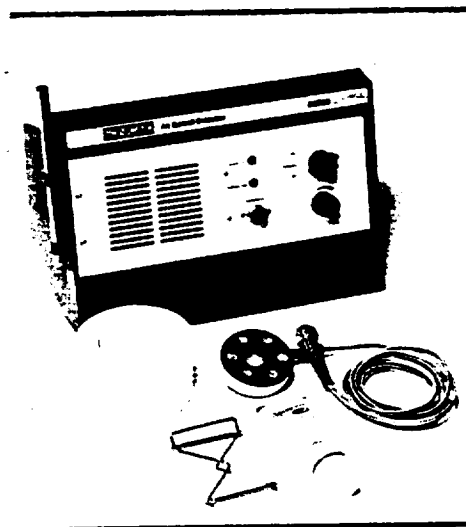
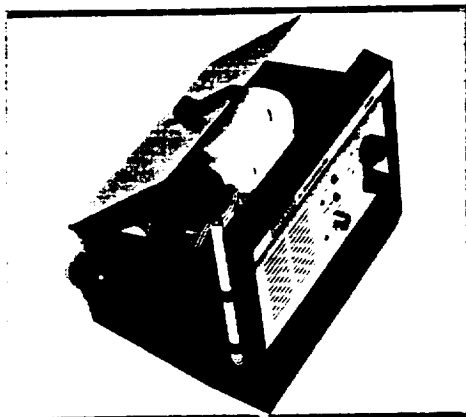
Simple transducer attachment.



Air Emboli Detector D206E

A simple and sensitive method for diagnosing and monitoring air embolism.

The Sonicaid D206E Air Emboli Detector is designed specifically for use during operative procedures in which there is a risk of venous air embolism. Using a Doppler ultrasonic technique the early detection of a potentially fatal complication of venous air embolism can be made allowing action to be taken before it becomes apparent by other means of monitoring.



The air embolism is detected using a wide angle ultra-sound monitoring transducer operating at a frequency of 2MHz. Interfering signals from such sources as electrocautery are avoided by sensing the signal and disabling the audio and chart recorder output for the duration of the interference.

Embolism Event Recorder

An important feature of the unit is that a chart recorder drive signal is provided. The signal is processed so that it only responds to air emboli thereby providing a simple method for recording any air emboli event that may occur during the operation procedure.

Principle of Operation

The D206E generates a continuous 2MHz ultrasonic signal which is reflected by blood cells and vessels. By use of the Doppler technique the reflected signal from moving structures is converted into an audible sound. When air, in the form of an embolism, passes through the path of the ultrasound signal, a high-pitched "chirping" or "scratchy" sound is produced by the change in 'reflectivity' at the blood/air interface.

References

1. Albin MS, Babinski M, Maroon JC, et al: Anesthetic management of posterior fossa surgery in the sitting position. *Acta Anaesthesiol Scand* 20: 117-128. 1976
2. Edmonds-Seal J, Prys-Roberts C, Adams AP: Air embolism. A comparison of various methods of detection. *Anaesthesia* 26: 202-208. 1971
3. Michenfelder JD, Miller RH, Gronert GA: Evaluation of an ultrasonic device (Doppler) for the diagnosis of venous air embolism. *Anesthesiology* 36: 164-167. 1972.
4. Gildenberg P.L., O'Brien R.P. et al., "The efficiency of Doppler Monitoring for the Detection of Venous Air Embolism". *J. Neurosurg.* 54: 75-78. 1981.

Specification

Safety

Fully mains-isolated patient circuitry designed to conform to the following specifications:
IEC 601 Part 1 class 1
BS 5724 Part 1 class 1
UL 544 & CSA C22.2 No. 125 (1979)

Power Supply

100 - 125V, 200 - 250V, 50/60Hz
8 Rechargeable Nickel-Cadmium cells

Battery Life

Approx. 10 hours between charges.
Charging time 14 hours from full discharge

Controls & Connectors

'Off/charging/on' switch
Volume control
'Power on' LED indicator
'Battery low' LED indicator
Transducer socket
Headset jack
Additional protective Earth terminal
Waveform output
Fuses (2)

Accessories

Transducer, lycra bandage, buckle, headset, tube aquasonic gel, power cable, instructional tape cassette, operating handbook, spare fuses, miniature jack plug.

Dimensions

185 x 270 x 195mm

Weight

3.25 kg, complete with accessories

Ordering Information

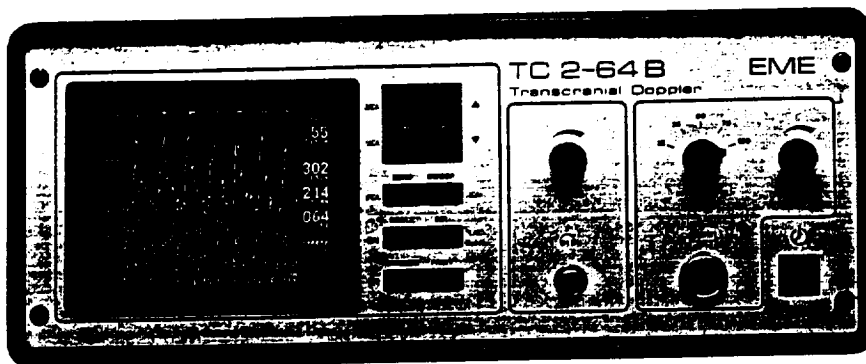
Please quote part numbers when ordering **Sonicaid Part No.**

D206E Air Emboli	
Detector	8340-6902
(incl. accessories)	8340-6908*
Aquasonic 100 (tube)	1300-0152
Aquasonic 100	
(0.25 litre bottle)	1300-0153
Aquasonic 100	
(4 litre container)	1300-0154
Monitoring	
Transducer	8340-6901
Stethoscope Headset	

Specifications are subject to change without notice.

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Instrument Description



The TC2-64 Transcranial Doppler is a 2 MHz pulsed ultrasound Doppler velocimeter for the examination of intracranial and extracranial blood vessels. It incorporates a built-in 64-point sliding-average FFT spectrum analyzer with a 132 spectral line resolution on the 5" (12 x 9 cm) monitor screen.

A choice of eight different velocity scales (4 bidirectional, 4 unidirectional) display velocities of up to 400 cm/sec or alternatively as Doppler shift in kHz (up to 10 kHz). Sweep speeds of 3, 5, 8 or 15 seconds are selectable and there is a frame freeze facility.

A built-in computer ensures simplicity of operation by adjusting such parameters as p.r.f., low-pass filters, etc., so as to optimize the spectral display and minimizing "aliasing" at high velocities. The monitor also displays a symbol for the direction of flow (towards or away from the probe), depth of the sample volume, cursor setting, mean velocity, pulsatility index (Gosling), patient ID number and vessel label (if applied).

The Doppler signal is reproduced by a built-in loudspeaker, but the use of the high-quality standard headphones is recommended. An adjustment of the ultrasonic output from 10 to 100% ensures that safety recommendations can be implemented without restricting flexibility of operation. A gain control adjusts the sensitivity of the spectrum analyzer to the strength of the Doppler signal.

Digital/analog input/outputs permit connection to video-printer, computer, strip-chart printer, monitors, etc. Hard-copy documentation can be provided by a dot-matrix or video printer. Secondary functions of the operating buttons are used to label left and right sides as well as main intracranial vessels. A remote control allows operation from the bedside.



The TC2-64B Multifrequency Transcranial Doppler is identical to the TC2-64 with the addition of 4 and 8 MHz facility with a switchable probe holder.

Optional extras

A wide range of probes are available for monitoring, pediatric and other specialized extracranial and intracranial applications.

A quadruple-action foot-switch leaves the hands free for compression manoeuvres.

The TC/PC Interface conveniently connects the TC2-64 to a suitable computer.

A clip-on vinyl pannier ensures safe and easy transport of probes, gel and accessories.

An upgrade kit is available to upgrade the TC2-64 to the multifrequency 'B' version.

Weight: 9.9 kg (21.8 lbs)

Height: 15 cm (6 in)

Width: 41 cm (16 in)

Depth: 35 cm (14 in)

All dimensions without carrying handle.

For further information on this or any of EME's family of TCD instruments, contact your local distributor or EME directly.

This equipment is designed and constructed to conform to the requirements of IEC-1 Class 1, UL 544, CSA C22 2 No: 125 (1979), BS 5724-1 Class 1, VDE 0750 and other international safety standards.

Since we are continually seeking to improve our products and to make use of the latest technical innovations, these details are subject to change without notice.

Local regulations may require some variations.

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ORIGINALITY
OF YOUR QUALITY

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(800) 323-EDEN
Fax: (206) 656-8331

Versadopp® 10

DU Diagnostic
Ultrasound
corporation

THE VERSADOPP 10 DOPPLER

The **Versadopp 10** is a pocket sized, pulsed, ultrasonic Doppler instrument which extends the capability of the ordinary stethoscope; sensing **blood velocity** rather than only detecting sounds.

SENSITIVE AT THE RIGHT DEPTH

The **Versadopp 10** virtually eliminates noise from the motion of the instrument by not sensing depths near the skin surface. When the power switch is depressed, ultrasonic waves are transmitted from the transducer to arteries at depths between 0.1 cm and 1.75 cm. A small amount of ultrasonic wave energy is reflected and shifted slightly in frequency by moving blood cells (Doppler shift effect).

The **Versadopp 10** sensor receives the reflected wave energy, and translates the frequency shift into an audible signal. This signal is amplified and transmitted through a stethoscopic headset, giving an accurate representation of blood flow velocities. The **Versadopp 10** tissue penetration range is optimal for evaluating arterial flow; systolic blood pressure, peripheral vascular disease screening, occlusion screening, mapping location of arteries for placement of catheters, and penile arterial flow.

RUGGED AND CONVENIENT

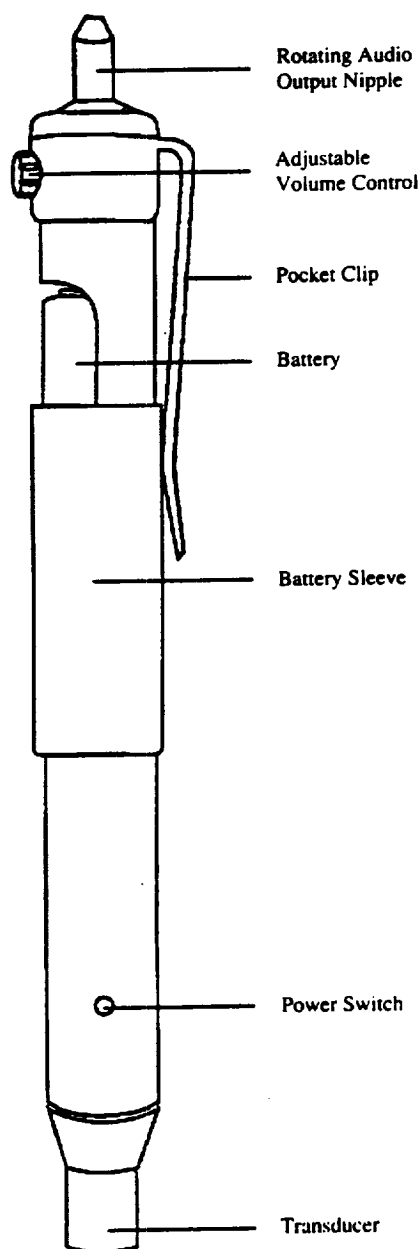
The stainless steel housing is rugged enough for years of use, and provides electromagnetic shielding from radio frequency interference. A standard stethoscopic headset fits on the rotating, audio output nipple, allowing the instrument to be positioned freely during use. The **Versadopp 10** may be sterilized by ethelene oxide gas (remove battery) for use intraoperatively, and covered by a latex probe cover for use in isolation cases.

SAFE AND EFFECTIVE

The high receiver efficiency of the transducer provides for patient safety through the use of low ultrasonic power.

PRECISE FLOW SOUNDS

The single crystal design of the **Versadopp 10** provides flow sounds more precisely related to flow velocities than older, two crystal designs. Vascular professionals commonly recommend holding the **Versadopp 10** at a 45 degree angle to the vessel being examined, for best performance.



Versadopp® 10



ACTUAL
SIZE

SPECIFICATIONS

ULTRASONIC FREQUENCY	10 megahertz (+ or - 3%)
TRANSDUCER DIAMETER	6.5 mm
SENSING RANGE (DEPTH)	0.1 cm to 1.75 cm
OUTPUT	Audio to standard stethoscope (supplied)
BATTERY	4LR 44 or PX28L
BATTERY LIFE	Approximately 6 months ordinary clinical use (PX28L)
DIMENSIONS	16.25 cm X 1.65 cm
WEIGHT	54 grams (1.9 oz)

WARRANTY

Parts: We will provide exchange parts free of charge for up to 5 years from the date of original purchase.

Labor: We will repair the instrument free of charge for up to 1 year from the date of original purchase.

This warranty does not apply to products repaired or altered by anyone other than the DIAGNOSTIC ULTRASOUND Corporation. The DIAGNOSTIC ULTRASOUND Corporation shall not be liable for consequential damages. Since some states do not allow this exclusion of limitation of consequential damages, some of this limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

OUR 30 DAY EVALUATION POLICY

If for any reason you are not completely satisfied with your Versadopp®10 Doppler, you may return it in undamaged condition within 30 days for a prompt 100% refund.

DU Diagnostic
Ultrasound
corporation

P.O. Box 0789
Kirkland, Washington 98083-0789

(800) 331-2313
(206) 828-3860
FAX (206) 827-8324

To order, call our toll free number
(800) 331-2313

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THE HOFFREL™ MODEL 518 SD+

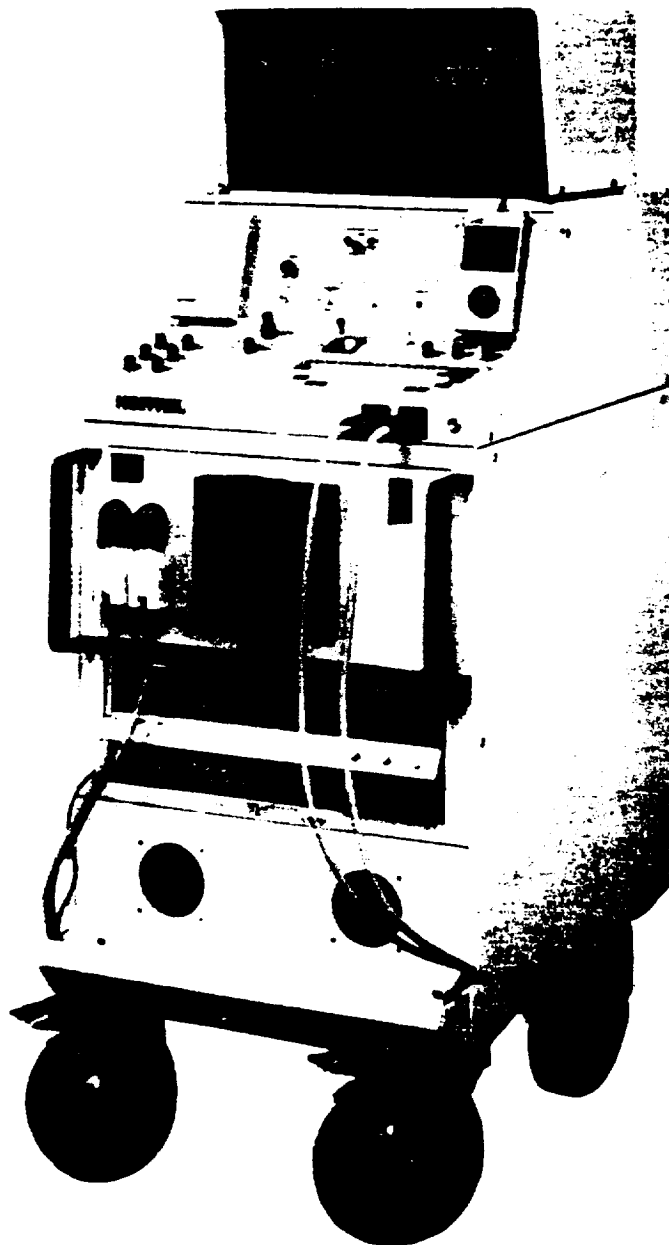


IMAGE + DOPPLER = DUPLEX

HOFFREL

Hoffrel Instruments Incorporated

SYSTEM SPECIFICATIONS:

Scan Angle:	Selectable 45, 60 and 75 degrees.
Frame Rate:	Selectable 15 or 25 frames per second.
Scanning Depth:	Selectable 2.5, 5, 9, 14, 17 and 25 centimeters.
Video Gray:	2-D, 64 levels (8 selectable positions) M-mode 16 levels (8 selectable positions) Spectral Display 16 levels 3 selectable Scroll Rates (lo, med, hi) also moving bar display (lo, med, hi).
M-mode:	Read only X2
Zoom:	Distance, Area, Perimeter calculations (joystick input). Velocity calculation. Angle determination.
Measurement Package:	Frame to Frame integration to help minimize noise
Integrate:	2-D and M-mode
SDC Display:	Selectable on/off (real time)
A-mode:	White on Black/Black on White (2-D and M-mode)
Video Inverse:	2-D and M-mode
Depth markers:	Servo
Scan Control:	Separate brightness and contrast controls.
Dual 9" Displays:	Separate Freeze controls.
Copy function:	Hard copy and/or Video tape of both displays. Full 9" displays of 2-D, M-mode and Spectrum Analysis. Both monitors turn left and right to facilitate viewing.
Membrane Keyboard Front Panel:	Input connectors for two transducers, user selectable. Durable, cleanable, resists coupling gel.
Remote Control:	All spectrum Analyzer controls. Video Cassette Recorder controls.
Footswitch control:	Mode, Freeze and Hard Copy.
Audio:	Two channels @ 4 Watts/channel
Sector Refresh:	Automatic sector refresh (updates sector image) while performing doppler studies.
Cursor Scan:	Automatic doppler cursor scanning to view all the gates available during live sector.
Ghosting Gates:	Allows operator to view any doppler gate during 2-D.
Scanning Modes:	A-mode, M-mode, 2-D
Cursor:	Vector cursor continuously adjustable through 60 deg. Transducer can be stopped anywhere in sector angle to perform M-mode or doppler studies.
Gain:	Continuously variable control of: Power Reject Near Far Slope Start
Pulsed Doppler:	Multifrequency operation: 2.0, 3.1, 3.8, 5.6, 7.5MHz. Sample Gate Size (frequency dependent) Min. 0.4 mm Max. 6.2 mm
Pulse length:	Selectable 4, 8, 15 cycles
PRF:	3 selectable fixed values for each probe frequency. The values are: fo/400 Lo, fo/280 Mid, fo/200 Hi
Ambiguity Indicator:	Alerts operator when the sample gate is out of allowable sampling depth.
Doppler Gate Depth:	Max. 15.2cm (frequency dependent)
Integrated Polaroid Camera or Mitsubishi Video Printer:	Front panel and footswitch control
Spectrum Analyzer (FFT):	Autotune: Automatic setting of Noise Level and Dynamic Range with manual override. Quantify: Automated calculation of peak frequency and mode frequency. Automated time and frequency cursors. Real-time clock and date display. Vessel annotation display. Remote control.
Video Cassette Recorder:	JVC BR6400U with remote control. ½ inch VHS format. Direct drive system. 4-head system. Shuttle search at 10 times normal speed. Variable-speed playback from still to 5 times normal, in forward and reverse. Selectable audio dubbing.
Storage bin:	Front accessible.
Dimensions:	Height 57", 145cm Width 20.5", 52cm Depth 31", 78cm Wheel Size 8", 20cm Weight 398 lbs., 181kg
Power:	120v/60Hz @ 6.1 amps. (732 watts) Integrated Isolation Transformer

Specifications subject to
change without notice

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(203) 866-9205
TELEX: 752745 HOFFREL UD
HPN 227-00068 (4/86)

HADECO

MINI-DOPPLER ULTRASOUND BLOODFLOW DETECTOR ES-100X



THE ADVANTAGE OF HADECO TECHNOLOGY

- Hand held design
- Built-in speaker
- Five interchangeable probes
- Automatic power "OFF"
- Battery operated
- Printer Output



Doppler Ultrasound Probe Model P81

A large flat probe for use with MedaSonics VERSATONE® Doppler. Ultrasound frequency: approximately 2.4 MHz.



- Used during neurosurgical procedures performed in the upright position for the detection of venous air embolism.
- Improved shielding allows use of this Doppler probe without electrocautery interference when VERSATONE is operated on battery power.
- Detects internal motion – heart muscle, heart valves, and blood flow.
- Probe incorporates two sending crystals and two receiving crystals to give wide angle coverage.
- Rapidly interchangeable with other VERSATONE™ Doppler probes.

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Title: Assessment of an In-suit EVA Doppler bubble detector.
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 Originating NASA Organization: Space and Life Sciences Directorate/Life Sciences Project Division
 Performing Organization (if different): General Electric Government Services
 Contract/Grant/Interagency/Project Number(s): NAS 9-17884
 Document Number(s): CR 185692 Document Date: _____

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In-Suit Doppler Technology Assessment

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 Typed Name of Project Officer/Technical Monitor

SE4
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Cindy Moody
 Signature

23 Apr 92
 Date

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☒ Approved

☐ Not Approved

Carolyn L. Huntoon
 Typed Name of Program Office Representative

SA
 Program Office and Code

[Signature]
 Signature

4/29/92
 Date

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